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(54) Title: METHOD OF PERFORMING OPHTHALMIC SURGERY
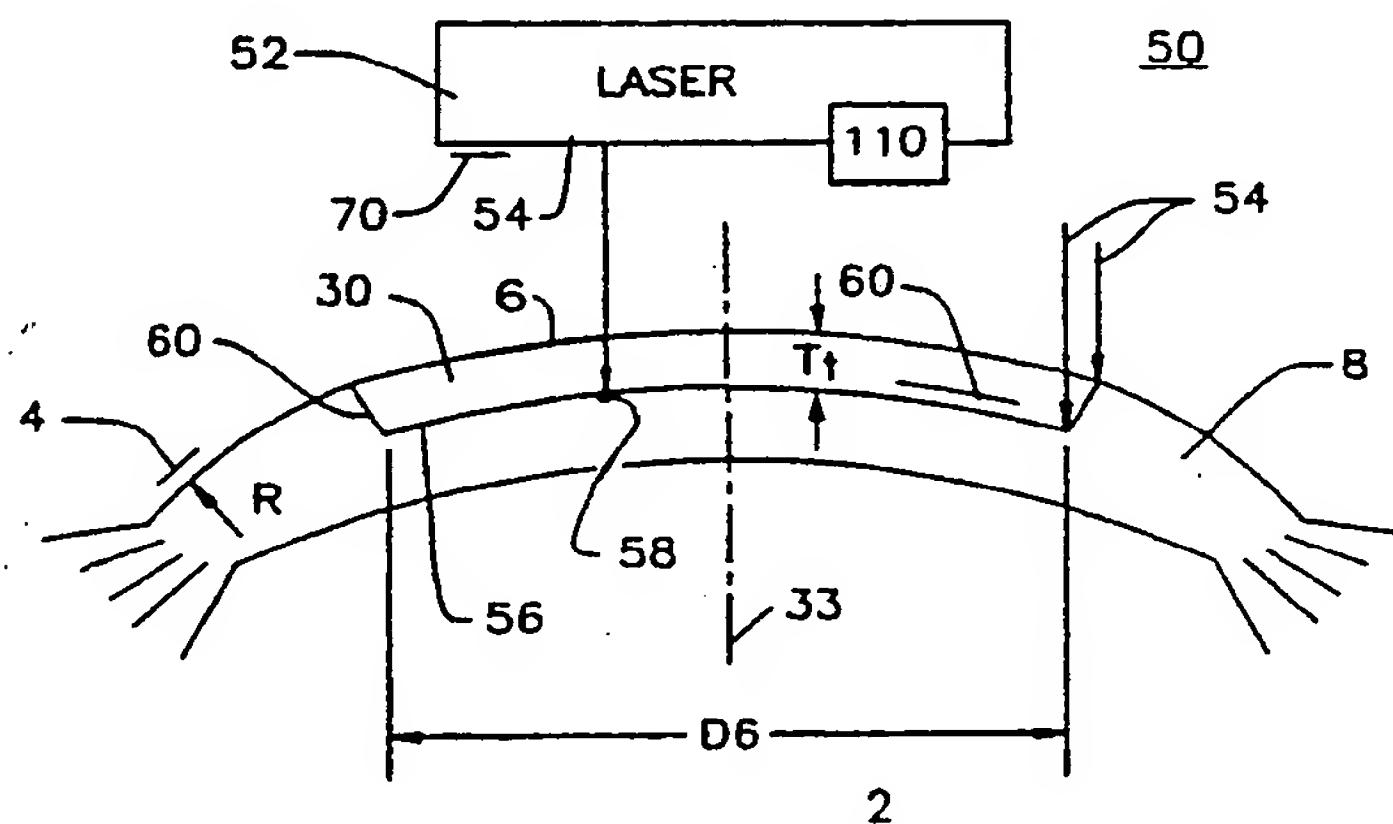
(57) Abstract

Low energy, ultra-short (femptoseconds) pulsed laser radiation is applied to the patient's eye (2) in one of a number of patterns such that the exposed ocular tissue is ablated (56) or excised (54) through the process of optical breakdown or photodisruption in a very controlled fashion. The process can be gentle enough that the invention makes possible the performance of a number of surgical procedures that in the past could not have been performed at all, such as capsulorhexis, or were performed in a fashion that provided less than an ideal result or excessive trauma to the ocular tissue. Such latter applications include the making of incisions for corneal transplantation, radial and arcuate keratotomy, and intra-stromal cavitation. Using the laser inside the eye allows the surgeon to perform glaucoma operations such as trabeculoplasty and iridotomy, cataract techniques such as capsulectomy, capsulorhexis and phacoablation, and vitreoretinal surgery, such as membrane resection. The various procedures are accomplished by controlling energy flux or irradiance, geometric deposition of beam exposure and exposure time.

METHOD OF PERFORMING
OPHTHALMIC SURGERY

This application describes various surgical procedures employing a femptosecond laser described in a co-pending application of Shui T. Lai.

FIELD OF INVENTION

The invention relates broadly to surgical procedures of the eye. Such procedures include operations on the outer covering of the eye, or cornea, the iris and trabecular meshwork, the lens, and the vitreous and retina.

BACKGROUND OF THE INVENTION

In many cases, the procedures proposed have been performed in the past, but they have been accompanied by inaccuracy, trauma or ocular damage. In others, they have never been capable of performance because of surgical or technical considerations.

United States patent 4,309,998, Aron nee Rosa et. al., issued January 12, 1982, described the process of optical breakdown and photodisruption, whereby tissues, transparent or not, to a given wavelength of laser radiation can be excised or ablated by sharply focusing the beam at a specific point in the tissue while achieving a local power density at the site above the threshold (greater than 10 12 Watts/cm2) for optical breakdown,

a complex process involving ionization, plasma formation, and mechanical disruption by secondarily propagated waves. In this patent, the inventors used a YAG laser, emitting at 1064 nm, with pulse widths in the range of 20-400 ps and energies in the range of 2-5 mj to ablate opacities from the lens of the eye, open posterior lens capsules, and cut vitreous membranes.

In their publication, "Ophthalmic Neodymium Yag Lasers", Keates et. al. describe the basic principles underlying photodisruption with lasers. The definition of power density is given as the ratio of beam energy in Joules divided by pulse length in seconds times focal spot area in square centimeters. Thus the shorter the pulse length or the smaller the spot, the greater the power density, which is the determinant in achieving optical breakdown, whose threshold is given as 10^{12} W/cm^2. Also, it is described that high pulse power and low energy pulses are preferred for cutting or perforating tissue, and that low pulse power and high energy pulses is associated with thermal and biophysical damage mechanisms. By using shorter pulses, an appropriate power density can be achieved in any tissue with a lower energy level, which reduces shock waves and adjacent tissue damage.

United States patent 4,907,586, Bille and Brown, issued March 13, 1990, describes the use of the photodisruptive process for corneal and other eye surgery. In this patent, a quasi-continuous picosecond pulse width laser is used to create

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optical breakdown in various tissues. The inventors describe, in general, the types of procedures that may be attempted with such a laser.

One of us (Shui T. Lai) has described technology for producing laser pulses in the femtosecond range, which, as based on the above discussion, allows high power densities to be achieved at much lower energy levels than any described in the art. Experimentally, we ablated tissue by photodisruption at various pulse widths and energy levels and have demonstrated the attainment of superior results with respect to the procedures described herein when operating in the femtosecond range as opposed to the picosecond range, with respect to pulse width. Light and electron microscopy have clearly demonstrated less adjacent damage, sharper incisions, and the ability to more accurately localize the surgical interaction, which is mandatory for optical success.

Corneal operations are typically performed for either therapeutic or optical considerations. In the therapeutic class are such procedures as lamellar keratoplasty and penetrating keratoplasty or corneal transplantation. The classic operation of lamellar keratoplasty is designed to remove scarred, irregular or opaque corneal tissue from across the visually critical central optic zone of the cornea and replacement with a partial donor cornea to restore the corneal shape and clarity, thereby improving vision. It relates also

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to other operations on the anterior cornea designed primarily to produce changes in the optical imaging of the cornea, thereby correcting optic errors of the eye, such as myopia (nearsightedness), hyperopia combinations thereof.

The operation of partial thickness lamellar keratoplasty to remove corneal opacities has been practiced for many years (see Brightbill,FS, Corneal Surgery, Chapter 33, C.V. Mosby Co., St. Louis, 1986). It has classically been performed by direct mechanical removal of a circular disc of tissue of constant thickness and replacement thereof with a similarly shaped piece of donor corneal tissue. The optical quality of the final cornea has frequently been known to be irregular or with some interface opacity, and often results in reduction of vision from normal. More recently, this procedure has been performed with a high-speed mechanical microkeratome to effect detachment of the anterior disk both from the patient's cornea and from the donor's cornea. However, this technique is technically difficult and accompanied by incomplete or irregular resections, resections of inappropriate depth, and can cause penetration into the eye.

In penetrating keratoplasty, a partial diameter but full thickness section of the patient's cornea is removed and replaced with a donor corneal button similar in size. Typically, the walls of the incision are vertical, or parallel to the visual axis. This provides a button whose walls are a

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portion of a cylinder. Also, the transplant button is typically round, as this facilitates use of mechanical trephines. However, many surgeons believe that round buttons may not be ideal, for several reasons, involving healing, rejection, and endothelial cell population transplanted. However, there is no technique at present to allow for cutting corneal buttons of any shape, with accuracy.

Also, some surgeons believe that walls other than vertical may decrease various complications, such as wound leak, astigmatism, etc. This is not accomplishable by any means.

This operation is notoriously accompanied by high astigmatism following the surgery, which limits its success, and which is believed to result from the healing process of irregularly cut wound margins. Typically, some trephine blade is used to make most of the incision, which is then completed manually with scissors. Surgeons have long sought an ideal way to cut corneal tissue as evidenced by the number of different trephines developed.

Corneal surgery is also performed frequently for modifying the optical or refractive power of the eye. Such operations fall into different categories or approaches. They include the lamellar techniques, whereby corneal tissue is removed from within the cornea, leaving its anterior outermost structure intact, incisional techniques, whereby cuts are made through

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the anterior surface and to deep in the cornea, thereby causing secondary compensatory changes in the curvature of the anterior cornea, and, most recently, direct ablation or removal of the anterior cornea in a controlled fashion, using an ultraviolet laser, to produce a new surface with different curvature.

Barraquer teaches the general art of altering the anterior corneal curvature of the eye to effect changes in refraction, or optical imaging of the eye, with the operation of keratomileusis, a form of lamellar keratoplasty. (See IBID, Chpt. 37). In this procedure, a circular lamellar disc of constant thickness centered on the visual axis is removed from the front of the patient's cornea with a high-speed mechanical microkeratome. Following said removal, called a lamellar keratectomy, the resected lamellar disc of constant thickness is placed onto one effect modification in shape to produce a lenticule with refractive optical power. Although operationally different, both devices effect the production of a refractive corneal lenticule. The lenticule is produced by volumetric mechanical removal of stromal tissue from the cut and exposed corneal stromal surface of the resected lamellar disc. Such tissue removal may be greatest in the center of the disc, which allows for correction of myopia, or toward the outer periphery, which allows for correction of hyperopia. In any event, the tissue removal is usually such that there is a smooth and regular transition of thickness as one traverses the optically modified (optic zone) area. Following tissue removal from the

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disc (now called a lenticule), it is replaced onto the patient's cut stromal surface remaining behind after the initial keratectomy. Said replacement results in a new anterior corneal curvature and alteration in the optic imaging of light by the cornea.

In addition, the mechanical microkeratome has also been used in two recently developed lamellar refractive procedures - in-situ keratomileusis and hyperopic lamellar keratectomy. In in-situ keratomileusis, the microkeratome is used to detach a thin slice of constant thickness from the patient's cornea. This is followed by a second keratectomy with the microkeratome, smaller in diameter than the first and concentric within the confines of the first. The initially resected disc is then replaced atop the bed. The second keratectomy also resects a disc of parallel faces or constant thickness. When the cap is replaced, it drops into the cavity, thereby causing flattening of the anterior cornea. The degree of flattening and optical correction is related to the depth and diameter of the second resection. This procedure is to be distinguished from classic keratomileusis performed with a laser for making the second, or optical, ablation, as the physical process is different and in-situ keratomileusis provides a larger functional optical zone, greater refractive correction and greater stability.

In hyperopic lamellar keratectomy a lamellar disc of corneal tissue is deeply removed and simply replaced to effect a

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correction of hyperopia. The amount of correction is related to the diameter of the resected disc. However, experience has shown that the mechanical microkeratome has the potential of becoming stuck in its passage across the eye, of producing a surface of irregular or poor quality, of being inaccurate with respect to diameter and thickness, all of which compromise the result obtained. Also, there is technical difficulty in using the microkeratome, despite its being automated recently.

Another category of corneal procedures consists of incisional techniques. Here, as in radial keratotomy, for example, the surgeon makes a series of incisions deep into the cornea, sparing a central incision free zone. This results in flattening of the cornea and correction of myopia. Or, various other geometric patterns of incisions may be made, such as transverse or arcuate. These are typically used to correct astigmatism. The major limitation with these techniques is the inability of the surgeon to cut precisely in the desired location and in a reproducible fashion, especially with respect to the length, depth and perpendicularity of the incisions. This results in a lack of reproducibility and inaccuracy. It is well established that incisions too short lead to undercorrection, too long to overcorrection and bothersome visual symptoms, and deviation from perpendicularity, or oblique incisions, like shallow incisions, to undercorrection and instability. Thus, the inability to plan, has been a major drawback.

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A characteristic of the foregoing discussion of operative procedures is that they all attempt to spare the anterior central corneal structure from surgical damage. This is in contrast to the recently developed excimer laser surgical procedures where the anterior surface is progressively ablated and destroyed by the surgery. United States patent 4,732,148, L'Esperance, issued March 22, 1988, discloses a method of applying ultraviolet radiation to the anterior cornea (photorefractive keratectomy) in order to correct the optical errors of myopia, hyperopia, and astigmatism. Unfortunately, the delicate anterior membrane complex of the patient's cornea (primarily Bowman's membrane) is destroyed in the process of removal, leaving a cornea which is anatomically, and perhaps physiologically, abnormal. In addition, two other drawbacks of this method have been noted. The first is the production of haze within the operated cornea, which can be permanent, and which may be associated with visual symptoms or reduction in vision. Haze has been attributed to acoustic shock waves, induced by the laser beam of high energy, propagated in the cornea. Second, the anatomically abnormal cornea develops a healing response such that the outermost epithelial layer, regenerated over the operated area from peripheral unoperated epithelium, frequently demonstrates hyperplasia or thickening postoperatively. This can cause gross inaccuracy or instability of the obtained optical result. Also, pain and delayed rehabilitation along with the long-term use of medications that may cause glaucoma are needed. For this

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reason, surgeons seek procedures capable of correcting optical errors of the eye while sparing the central cornea.

United States patent 4,903,695, Warner et. al., issued February 27, 1990 disclosed a method of performing Barraquer's classic keratomileusis operation using an ultraviolet or infrared laser to effect the tissue modification step, thereby replacing the cryolathe and BKS device. It also circumvents laser damage to the anterior cornea. However, the method requires the use of a mechanical microkeratome to first detach a circular disc of tissue from the patient's cornea, which has limitations as previously described. Following this mechanical cut, the laser irradiation is applied selectively to the cut stromal surface left behind on the patient to remove tissue in a controlled fashion such that when the initially resected disc is replaced onto the bed from which it was removed, a new curvature is imposed onto the anterior corneal surface. In this teaching, the "predetermined curvature" imposed on the ablated corneal bed is intimately related to the final desired anterior curvature of the cornea, and is in fact equal to the final radius of curvature desired minus the thickness of the disc resected by the microkeratome. It is important to note that radiation is applied to resect from the bed, as clearly described in the drawings, a lens of optical power from the cornea, not to create a trough of constant depth, as is the basis of in-situ keratomileusis, which induces a curvature change by a different physical process.

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The corneal techniques described above have met with several shortcomings, as partly described. These consist in the inability to precisely and reproducibly cut living corneal tissue with a minimum of trauma to the cornea. The mechanical and manual techniques best exemplify this limitation. When cutting technology have not demonstrated the ability to cut with minimal trauma and maximal control. One observes a tissue interaction zone which is too large for precise tissue removal, no cutting at all if the power density is below the threshold, or adjacent tissue damage from the energy levels used.

Lasers have been used in glaucoma surgery for years. There are two major classes of glaucoma, open angle and closed angle. In open angle glaucoma, there is difficulty in the eye's intraocular fluid exiting from the eye, thus raising the pressure within the eye, causing glaucoma. The basic problem is the outflow channel for fluid, which does not function well. For this reason, a number of operations have been developed to provide increased outflow. In closed angle glaucoma, the problem lies more in the internal structure of the eye, where various abnormalities allow the pressure to build up behind the iris of the eye, causing a displacement, which in turn compresses or occludes the outflow channel, which is more or less normal. Thus, operations to correct open angle glaucoma are geared to providing outflow from the eye, whereas closed angle glaucoma is corrected by making a full-thickness hole through the iris to allow the free movement of fluid from the

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back of the eye, where it is made, to the front of the eye, from where it exits the eye.

Typically, two surgical approaches have been utilized. The oldest and most common is utilizing a laser such as an argon laser to achieve the desired effects in trabeculoplasty and iridotomy by photocoagulation, or the vaporization of tissue. In filtration procedures such as trabeculoplasty, minor restructuring of the tissue with partial or complete penetration is accomplished by thermal effects of the laser, thereby causing a change in structure of the trabecular meshwork, which is part of the outflow system of the eye. Surgery alters the structure such that the intraocular fluid can escape from the eye more easily, thereby reducing the eye's pressure in glaucoma patients. Also, the operation of sclerostomy is similarly performed, either from within or without the eye, to create a drainage channel for the intraocular fluid. Also, the operation of trabeculectomy is another modification, whereby a partial thickness flap of the eye's wall, the sclera, is opened, a drainage opening made into the eye itself, and the flap replaced as a partial thickness protector for the interior of the eye. Recently, lasers such as the holmium, an infrared laser have been used, in attempts to provide some of these perforations.

In closed angle glaucoma, an iridotomy, or total penetration through the iris is desired. In addition to using

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photocoagulation or photovaporization, one can also use
photodisruption. The disadvantages of all these techniques are
ocular trauma, especially in photodisruption, where each laser
pulse produces a significant shock wave that can damage the
delicate intraocular structures.

Lasers have also been used in cataract surgery for some time.
This includes both for excising the posterior lens capsule,
when opacified, and for delivering energy to the lens itself
for ablating its interior substance, both to create an opening
at the visual axis or to shorten the time of secondary
phacoemulsification surgery by first liquefying the interior
lens substance, which uses ultrasonic energy to remove the lens
material and which is traumatic to the posterior lens capsule
and intraocular structures. It is felt that by first ablating
the lens (phacoablation) that the time needed for the
ultrasound will be reduced. Unfortunately, the lasers proposed
thus far, Nd:YAG and Nd:YLF have a considerable acoustic shock
component in posterior capsule of the lens to remove an
opacity, shock waves from the currently used Nd:YAG lasers have
been shown to be able to cause complications in the posterior
eye. Cataract surgery, as presently performed, requires the
opening of the anterior capsule of the lens to allow the
surgeon access to the lens itself. Currently, no laser has the
control and gentleness of beam that allows a smooth and regular
opening, or capsulorhexis. To date, this opening has been

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created manually, with a needle, and this can result in complications if torn irregularly or inappropriately.

Behind the lens, or in the posterior segment of the eye, lies the vitreous humour and retina. Currently, lasers utilizing photodisruption can be used to cut or ablate membranes within the vitreous cavity, but only with significant shock and only at a safe distance from the retina. Surgeons seek a fine cutting laser with minimal shock wave that can allow membranes close to the retina to be resected.

Also, many patients have retinal pathology, such as subretinal membranes or blood vessels. In most instances, these conditions are not treatable as they would cause substantial damage to vision, as the functional part of the retina overlies the abnormal pathology, and attempts to remove or ablate the pathology lead to destruction of the overlying retina. A laser capable of ablating behind the retina with minimal thermal or shock component would allow many patients a surgical option for cure of their blindness.

SUMMARY OF THE INVENTION

It is an object of the invention to provide improved surgical techniques for performance of currently used operations in several areas of the eye, such as corneal, glaucoma, cataract, vitreal and retinal.

It is a further object to improve such current ophthalmic surgical procedures by reducing the ocular trauma and complications associated with them by performing surgery with laser radiation of lower energy, and higher power density, than currently used lasers.

It is another object to improve the results of and allow more reproducible performance of operations on the cornea, such as lamellar and penetrating keratoplasty, keratomileusis, keratotomy, both linear and lamellar, whether for therapeutic or refractive purposes.

It is a further object to reduce optical (refractive) errors by obviating the need for cumbersome and complicated mechanical devices (such as the mechanical microkeratome, cryolathe and BKS device) from said surgery.

It is a specific object to achieve the preceding objects by providing procedures to reduce myopia, hyperopia, astigmatism, irregular astigmatism, presbyopia, optical aberrations of the eye such as spherical aberration, or any combinations thereof in a manner that will improve results and reduce tissue damage.

It is an object to provide a method (laser microkeratome) for resecting from a cornea a parallel-faced lamellar disc (lamellar keratectomy) without refractive power whether for

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therapeutic or refractive surgery while eliminating the need for manual dissection or mechanical microkeratome.

It is a further object to use the said laser microkeratome to perform on the cornea a lamellar keratectomy with non-parallel faces, isolating or removing from the cornea a lamellar refractive lens, such that the cornea is left with a new anterior surface with different curvature, thereby allowing the direct correction of optical refractive errors.

It is a further object of the invention to use the said laser microkeratome to perform on the cornea a lamellar keratectomy of varying diameter, whose thickness may be constant or varied, such that following the ablation, with the lamellar disc in its original bed, hyperopia, with or without astigmatism, is corrected.

It is an object of the invention to provide a means of performing keratomileusis-in-situ with increased accuracy and precision while eliminating one or both steps of mechanical microkeratome resection on the patient's cornea.

It is an object to accomplish performance of a variety of corneal surgical procedures while providing for a relatively normal anterior corneal structure in the critical central optic area at the conclusion of the procedure.

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It is an object to accomplish the above by visible or infrared wavelength laser irradiation to the cornea, using any commercially available laser, with or without a beam control scanner, except in the case of keratomileusis-in-situ, where an ultraviolet laser may be used.

It is a further object to allow performance of glaucoma operations with increased accuracy and precision, such as sclerostomy, trabeculectomy, trabeculoplasty and iridotomy while reducing shock waves to the interior of the eye.

It is an object of the invention to allow the surgeon to open the anterior capsule of the lens of the eye in a controlled manner such that a smooth and regular opening (capsulorhexis), with predictable dimension, is achievable, thereby allowing safer insertion and fixation of intraocular lenses during cataract surgery.

It is a further object of the invention to alter the viscoelastic properties of the lens or to ablate it partially or entirely using laser radiation which reduces shock waves within the eye, thereby reducing complications.

It is a further object of the invention to alter the viscoelastic properties of the lens or to ablate it partially such that the anterior or posterior lens capsule undergoes a

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specific shape or curvature change calculated to correct optical refractive errors of the eye.

It is a further object of the invention to allow opening of the posterior capsule of the lens (posterior capsulectomy) without opening the eye, and to do so in a manner which reduces the shock waves and complications typically associated with such a procedure.

It is an object of the invention to allow the sectioning or ablation of pathologic membranes within the vitreous cavity of the eye with less trauma, thereby allowing the surgeon to operate closer to the delicate retina than heretofore possible.

It is an object of the invention to allow destruction of subretinal membranes or blood vessels while minimizing damage to the retina itself by focusing the radiation behind the retina and ablating the pathologic tissue while sparing the overlying retina.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described in detail with the assistance of the following drawings.

Fig.1 is a schematic of the eye, showing general reference points, including cornea, iris, lens, and retina.

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Fig.2 is a simplified side view of the cornea, as an elevation in section, through a plane intersecting and parallel to the visual axis, demonstrating a lamellar keratectomy of parallel faces.

Fig.3 is a side view of the cornea demonstrating the principle of the laser microkeratome in which laser radiation is used to perform a lamellar keratectomy.

Fig.4 is an elevation in section of the cornea demonstrating the principle of the laser microkeratome.

Fig.5 is an elevation in section demonstrating the production of a new, flatter corneal surface using the laser microkeratome.

Fig.6 is an elevation in section demonstrating the production of a new, steeper corneal surface, using the laser microkeratome.

Fig.7 is an elevation in section demonstrating the production of a new corneal surface using a deforming lens to allow ablation in two dimensions.

Fig.8 is a side view of the cornea demonstrating laser keratomileusis-in-situ, whereby laser radiation is applied to the stromal bed following a lamellar keratectomy.

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Fig.9 demonstrates in side view the keratectomy of constant depth produced in Fig.8.

Fig.10 demonstrates in side view a resected lamellar disc on a block which is being treated with the laser on its stromal surface.

Fig.11 demonstrates in side view the lamellar disc of Fig.10 following treatment whereby a circular cavity of constant depth has been produced.

Fig.12 is an elevation in section of a cornea following laser keratomileusis-in-situ demonstrating the repositioning of the disc and flattening of the central cornea.

Fig. 13 is an elevation in section demonstrating keratomileusis-in-situ, with ablation of the bed, for the correction of hyperopia.

Fig.14 is an elevation in section demonstrating keratomileusis-in-situ, with ablation of the disc, for correction of hyperopia.

Fig.15 shows the reconstructed and steepened cornea following laser keratomileusis-in-situ for hyperopia.

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Fig.16 is a frontal view demonstrating the correction of astigmatism by laser keratomileusis-in-situ.

Fig.17 demonstrates, in frontal view, the correction of combined hyperopia and astigmatism.

Fig.18 is a side view of the cornea demonstrating laser production of an intrastromal cavity designed for myopic correction along with an extension that allows for relaxation of Bowman's membrane.

Fig.19 is a frontal view of Fig.18 demonstrating the circular optic zone of the cavity produced and the larger diameter relaxation incision.

Fig.20 is a front view of a round penetrating keratoplasty incision.

Fig.21 is an elevation in section of the cornea demonstrating a full thickness penetrating keratoplasty incision.

Fig. 22 is an elevation in section demonstrating the production of a penetrating keratoplasty incision by laser.

Fig.23 is a frontal view of the cornea demonstrating various incisional patterns, some of which penetrate the anterior corneal surface (solid) and some of which do not (dotted).

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Fig.24 is a side view of the cornea demonstrating both anterior penetrating and intrastromal radial incisions made with laser radiation.

Fig.25 demonstrates laser iridotomy.

Fig.26 demonstrates the use of the laser for making incisions for glaucoma surgery and trabeculoplasty.

Fig.27 is frontal view of the lens of the eye demonstrating a smooth circular opening (capsulorhexis) made by a gentle laser beam and an irregular opening made by a laser with less refined cutting ability.

Fig.28 demonstrates, as an elevation in section, a laser anterior capsulectomy.

Fig.29 is an elevation in section of phacorefractive surgery.

Fig.30 demonstrates ablation of the lens substance to correct refractive errors.

Fig.31 demonstrates laser ablation of a vitreous membrane.

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DETAILED DESCRIPTION OF THE DRAWINGS

Fig. 1 demonstrates some of the eye's 2 generally designated landmarks. Most anterior is the cornea 4, whose curved anterior surface 6 and inner stromal substance 8 are shown. Posterior to cornea 4 is iris diaphragm 10. Behind iris 10 is lens 12, whose anterior capsule 14, posterior capsule 16 and internal substance 18 are shown. Also shown is vitreous membrane 20, retina 22, and an example of subretinal pathology 24.

Fig. 2 demonstrates the principle of a lamellar keratectomy. In this generic drawing, the keratectomy may have been produced by a mechanical microkeratome or by a laser. In this procedure a circular (in front view) section of tissue called a lamellar disc 30 is removed from the front of cornea 4. Disc 30 is of constant thickness T1 and of diameter D1. The keratectomy is centered upon the visual axis 33 of the patient's cornea 4. Because disc 30 is of constant thickness, the radius of curvature 36 of the keratectomized bed 38 is equal to the initial radius of curvature 40 the cornea 4 minus T1, and surface 41 of bed 38 is thus concentric to anterior corneal surface 6.

Fig. 3 demonstrates the principle of the laser microkeratome, generally designated 50, used to produce a lamellar photokeratectomy. The procedure is carried out by

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photodisruption with a laser 52 using a wavelength of radiation that is transmissive by the cornea 4. Internal corneal substance 8 is exposed to focussed laser radiation 54 over diameter D6, typically centered across the visual axis 33, of the eye 2. The laser energy is delivered across area of ablation 56 of diameter D6, which is circular in a frontal elevation and forms a line 56 appearing as an arc in the sectioned elevation which is Fig.3. The energy is delivered by focussing the laser beam 54 into a small laser spot 58, whose diameter can be selected. The spot is focussed at a level beneath corneal surface 6 equal to T4, the depth of the resection. Spot 58 is then moved in a scanning motion under computer control, along the line 56, which in fact represents the area of ablation of diameter D6. The spot size is chosen to minimize adjacent tissue damage, as is the irradiance of the laser beam itself. The laser beam is fired in a series of pulses, each pulse having a duration which we define as its pulse width. In the preferred embodiment, these pulse widths are ultrashort, preferably in the range of 10-400 femtoseconds to achieve a power density at the focal point 56 that will allow photodisruption to take place while keeping the beam energy or irradiance to a minimum. The energy level will vary depending on important to keep the energy level of the laser to a minimum, as the surface quality produced will become rougher as the energy is increased. The scanning of the spot can be carried out in a number of ways, depending on the design of the laser. For example, concentric circles, increasing or

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decreasing spirals, linear scanning while varying the length of each line to allow a circular pattern, etc. have been used with success. After scanning the area 56, which is a curved surface whose radius of curvature = R - T4, the delivery system may be programmed to ablate one or more additional concentric and adjacent surfaces 60, moving from posterior to anterior, to ensure complete separation of the anterior cap 64 from the bed 38 (Fig.2), defined by area of ablation 56 (Fig.3). Following ablation at depth T4, the laser spot is then scanned outward in a circular fashion beginning at depth T4, or at a slightly greater depth to ensure transection through surface 60, and ultimately scanned forward or outwardly until the scanned spot passes through the anterior corneal surface 6. When sectioning along line 60, which is part of a wall of a cylinder or cone, depending on the geometry or shape of the peripheral bevel or flange 60, the spot is typically scanned in either a continual spiral pattern or as a series of concentric circles, of the same or progressively increasing diameter. The exact pattern and energy levels may be altered as one ablates the vertical or sloping edge 60 of the disc 64 to ensure satisfactory ablation of the varying tissue materials. At this point the lamellar photokeratectomy has been completed. Its diameter is D6, it is of constant thickness T4, and it has a vertical edge, or, if desired, a sloping edge 60 of any desired angle. This keratectomy may be then left as is, or the lamellar disc can be grasped and removed by the surgeon in anticipation of further surgery on the disc 30 or the ablated bed 38.

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As a means of locating the area of ablation a preferred embodiment is shown in Fig. 4. A laser delivery system, generally designated 70, comprising the laser 72 and means for scanning 74 laser spot 58 in three dimensions, is physically coupled at a predetermined distance 76 to contact lens 78 which is transparent to the laser energy being delivered. The contact lens 78 comprises a curved surface 80 whose radius of curvature 82, approximately 8-12 mm, is somewhat greater than the typical radius of curvature of the cornea 36 (see Fig.3) to be operated upon, typically 7.7-8.2 mm. The index of refraction of the contact lens 78 is approximately that of the cornea, 1.376. Also, the contact lens may have a completely flat surface 78. This has certain advantages when performing intrastromal cavitation and lamellar keratectomy, as the laser need only scan in two dimensions in order to remove a lamellar disc of parallel faces. It also may simplify the distortion produced in the cornea from the plasma bubbles formed.

As shown in Fig.4, during the operation the curved surface 80 of the contact lens 78 is abutted to provide full contact with the anterior corneal surface 6, thus locating the intended area of ablation 56 at a known position with respect to the laser delivery system 70. (This may be accomplished or assisted by a peripheral corneal suction ring 81, as is well known in keratomileusis surgery. In this case, displacement movement of the contact lens within the ring in the x-y direction can be allowed by overlaping plates. This is important, as it allows

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the surgeon to center the applanation plate (if flat surface used) or contact lens surface on the visual axis of the patient so laser ablation is carried out with centration around the visual axis. The contact lens may, however, be simply placed against the cornea by slight pressure, or with assistance of a lubricant adhesive. This allows the laser spot 58 to be precisely located on intended area of ablation 56 and scanned across the entire area under computer 84 control. The upper surface 86 of the contact lens 78 may be flat to eliminate refraction of the laser beam 88, although any shape is possible and many shapes can be optically accounted for in the computer program.

Fig.3 can be used to describe a variant of the lamellar photokeratectomy using the laser microkeratome described in figures 3 and 4. This lamellar keratectomy procedure is performed to correct hyperopia.

In the present invention, a laser microkeratome is used rather than mechanical means. In this instance, the same laser 72, delivery system 74, and contact lens 78 are used. The energy considerations and scanning will not be repeated in detail. The principle of the operation is to vary the diameter D6 or the thickness T4 (Fig.3) of the resected lamellar disc 30. The principle of the operation is such that a controlled ectasia or forward bowing of the cornea results when a deep (70-90% of corneal thickness) lamellar disc 30 of small diameter, typically 5.5-7 mm, is resected and simply replaced, due to the

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pressure exerted from the intraocular fluid. This forward bowing causes a steepening of the central cornea. Diameter D6 and thickness T4 can be varied to achieve a range of curvature modifications, which may include those for correction of accompanying astigmatism, regular or irregular. Thickness T4 may be uniform or nonuniform across the area of ablation.

Fig.5 demonstrates a variant of lamellar photokeratectomy using the laser microkeratome described in Fig.4. In this instance, the same laser 72, delivery system 74, and contact lens 78 are used. The energy considerations and scanning will not be repeated in detail. The purpose of the operation described in Fig.5 is to create directly a new anterior surface 90 for the patient's cornea 4. The new surface 90 is designed to have a new curvature such that following its creation the patient's eye will now focus light in a new way. In Fig.5, this surface is shown as a flatter surface designed to correct myopia, but it may also be a steeper surface to correct hyperopia, or an astigmatic surface to correct astigmatism. It may also be aspheric to correct irregular astigmatism or alter spherical aberration or improve the optical functioning of the ablated cornea. In Fig.5, the computerized scanning delivery system 70 scans the spot 58 through the cornea 4 of the patient as in Fig.4 except that in this case the depth of the spot 58 below the anterior corneal surface 6 varies as prescribed to create the curved surface 90 desired. Scanning typically begins at the visual axis 33 and proceeds therefrom. Energy adjustments

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and minor alterations in the geometry at the edge of the disc may be necessary to fully and cleanly delimit the upper lenticule (which in Fig.5 is seen to be a lens with convergent refractive power).

In Fig.6 this ablation 100 is deepest at the visual axis 33 and tapers to meet corneal surface 6, or close to it, at diameter D7. The maximal depth of the ablation is T5. The optic zone diameter is D7, and the refractive power of this new surface is calculated from standard formulae. using its radius of curvature (calculated beforehand from the patient's refractive error, curvature, etc.), and the indices of refraction of air and corneal tissue. Following the ablation, the surgeon lifts off upper lenticule 102 which has been freed by ablation to reveal the new surface.

Fig.6 shows an area of ablation 100 whose central radius of curvature and which corrects hyperopia or farsightedness. For correction of astigmatism, a toric surface is produced with a major and minor radius of curvature, one of which 106 is shown in Fig.5.

Fig.3 also represents another embodiment of the invention. In this case, laser beam 54 is not referenced, or directly coupled physically, to the anterior corneal surface 6 by contact in order to localize the exact position of laser beam spot 58 with respect to the cornea 4. Instead, a scanning delivery system

70 is used in conjunction with a tracking system 100. Such delivery systems, including scanning and tracking systems that can precisely locate the laser spot 58 within the cornea 4, are already in use. Such laser corneal systems have been described in commercial literature by Intelligent Surgical Lasers, Inc., of San Diego, and Phoenix Laser Systems, of San Francisco. They have also been described in patents no. 4,848,340, Bille and Brown, issued Jul. 18, 1989, 4,901,718, Bille and Brown, issued Feb. 20, 1990, and 5,098,426, Sklar et. al., issued Mar. 24, 1992. Using such a system, the computer program directs the laser beam spot to be scanned through the corneal tissue in the same patterns and for the same purposes as described above for the contact lens 78 type of delivery system.

Fig.7 describes another embodiment of the invention. In Fig.5 laser beam spot 58 scans a curved surface in order to create a the new corneal surface 90. This necessitates tracking in three dimensions. However, if the contact lens delivery system is provided with a range of contact lenses, insertable into the base of the delivery system, or a fixed part of it, then the cornea 4 will be deformed into a new desired shape during laser ablation. In Fig.7 this contact lens 118 is such that the peripheral cornea is depressed more than the central cornea 122. Laser ablation is carried out in only two dimensions, as the three dimensional surface to be scanned in Fig.5 has now been reduced to a two dimensional surface 124, for practical purposes. Thus, by using only X-Y scanning, the Z axis

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tracking can be eliminated, which is a simplification. The
contact lenses which are part of the delivery system, can be
shaped with spherical, aspherical, toric, or any shape desired.
The contact lens in Fig.7 provides for correction of myopia, as
the postoperative cornea will be flatter. The shape of lenses
for hyperopic and astigmatic lenses will not be shown, as these
are easily derived.

Fig.8 demonstrates the operation of laser keratomileusis-in-
situ. Here the keratectomized bed 38 as produced in Fig.2 is
irradiated with a laser source to ablate the stromal tissue of
the bed 38. The laser source may be any laser capable of
ablating corneal stromal, whether by photoablative
decomposition, by photodisruption or photovaporization, and
using wavelengths from any part of the electromagnetic
spectrum. For example, an ultraviolet laser such as any
commercially available excimer laser could be used to carry out
photoablative decomposition, a visible wavelength laser such as
a Ti:Sapphire or Nd:YLF could be used for photodisruption and a
holmium, HF, or Er:YAG could be used for photovaporization.
Examples of lasers are for illustration, and any suitable laser
could be used. In addition, the laser source can be pulsed,
and its pulse duration can be short or ultra-short in pulse
width.

The laser radiation is distributed onto the central area of bed
38, is typically circular in frontal elevation and is of

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diameter D2, which is less than D1. D2 is typically 3-5 mm in diameter, whereas D1 is typically 6-8 mm. The irradiation is carried out scanned spot of very small diameter and guided by a laser's computer control system. The energy distribution of the laser beam 128 is constant over diameter D2 such that the keratectomy produced is of constant depth across D2. In addition, there are several variants as to how this resection may be done.

Using ultraviolet photoablative decomposition or infrared photovaporization, the tissue would be gradually ablated away until the end point is reached. With photodisruption the tissue can be ablated away similarly from front to back, or the keratectomy can be performed as described elsewhere in this document under the laser microkeratome.

Fig.9 shows the in-situ procedure at the stage after completion of the second keratectomy, which is on the bed following the first keratectomy of diameter D1 and thickness T1. This second or optical cut creates a cavity of constant depth T2, and with diameter D2. The radius of this second bed 130 is given as R-(T1+T2) and this bed is concentric with both the anterior corneal surface 6 and the bed 38. It is centered on visual axis 33. T2 is typically in the range of 20-200 microns, but can be otherwise.

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Fig.10 demonstrates a second way of performing keratomileusis-in-situ, whereby the optical or refractive cut is made onto the back stromal surface of the first keratectomized disc rather than onto the corneal bed 38. In this instance, following the initial keratectomy on the patient or donor cornea, the resected disc 30 of diameter D1 and thickness T1 is inverted and placed atop a concavity 132 of curvature 133 similar to the human cornea, though this is not necessary. The disc 30 may be placed into a closed chamber to keep humidity within and which is transparent to the wavelength of the laser used. The posterior stromal surface of this disc is then exposed to the laser radiation 136 as described under Fig.8, exposing an area of diameter D2 and removing a parallel faced lamella of tissue of thickness T2. The ablation is carried out with the center of ablation corresponding to the visual axis 33 of the patient, which has been previously identified and marked as in radial keratotomy surgery.

Fig.11 shows the completion of the process described in Fig.7. Here the parallel faced optical cut 140 has been completed. A circular section of cornea of constant thickness T2 and diameter D2 has been removed from the posterior aspect of disc 30.

Fig.12 demonstrates the completion of the in-situ procedure. Here the disc 30 has been replaced on bed 38. Because a cavity has been removed from either the disc 30 or from initial bed

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38, the cavity in either case will collapse and the posterior aspect of disc 30 will come into contact with either bed 38 or 134, depending upon whether the optical resection was performed on the disc 30 or the bed 38. Because of this collapse, the anterior curvature of the cornea will be altered to a new curvature 142 designed to correct the optical error of the patient. In this case the cornea is flattened and myopia is corrected.

Fig.13 demonstrates the keratomileusis-in-situ procedure for hyperopia or farsightedness. As in Fig. 2, a lamellar keratectomy is performed on the patient or donor eye using either a mechanical or a laser microkeratome. This removes, as in Fig.2, a disc 30 of thickness T1 and diameter D1. As in Figs.8-9, the bed of the patient is exposed to laser radiation by the methods described. In this case, however, the distribution of energy is different. Here laser energy is applied to ablate to a constant depth, but in this case there is no ablation in the immediate central area, centered on visual axis 33. The diameter of the non-ablated area, which is typically circular in frontal elevation, is given as D5. Thus the ablated area is seen to be a ring of ablation, concentric with visual axis 33, and whose width can vary from (D4-D5)/2 to (D3-D5)/2, depending on whether a blending flange or peripheral wing of blending is included to make for a smooth postoperative fit. The depth of the annular ablation is constant over the area ablated, and is given as T3. The height T3 and width of the projection D3 can vary to produce a range of desired

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optical effects. For example, the greater T3 is, the greater the amount of secondary curvature induced and the greater the amount of hyperopia corrected. Similarly, the correction will also be dependent on the width of the annular ablation, which can also be varied as desired.

Fig.14 demonstrates the comparable case for correction of myopia. Here ablation is carried out on the disc rather than the bed. The lamellar disc 30 has been placed in a concavity 132 with radius of curvature similar to the human cornea and laser irradiation is applied to its upper stromal surface 134. The anterior aspect is placed down against the holding block 132. The stromal surface is then exposed as in Fig.14 such that an annular circular ablation is effected sparing a circular central projection. The central projection has diameter D5 and is T3 in height. Varying height T3 of the projection and the width of the annular ablated zone will allow the surgeon to induce varying optical change in the patient's refractive error.

Fig.15 demonstrates the final appearance of the patient's cornea after replacement of the keratectomized disc. Because of the central cylindrical protrusion, whether on the keratectomized disc x or on the bed x, the central cornea of the patient is steepened and hyperopia corrected after placement of the disc because the annular cavity ablated

collapses and falls posteriorly, while the central apex at the visual axis 33 is prevented from doing so by the cylindrical protrusion.

Fig.16 demonstrates in frontal section of a cornea 4 the correction of astigmatism with this technique, with or without accompanying myopia or hyperopia. To correct astigmatism, the first keratectomy is performed in the usual manner. Then the bed, or keratectomized disc, is ablated as previously described. However, in this case, the ablated cavity 200 has an elliptical outline. The orientation of the ellipse with respect to major 202 and minor 204 axes is critical. In describing astigmatism, there is a meridian of the eye with maximal optical refractive power, and another, usually orthogonal, meridian with minimal refractive power, with the corneal astigmatism defined as the difference in corneal power of these two meridians. Thus, to eliminate astigmatism, the axis or meridian of greatest corneal power, here shown as 202, is aligned along the major axis of the ellipse, as greatest correction or reduction of corneal power takes place along the major axis. The reason is that the disc, when conforming to the ablation cavity will have greater opportunity to fall into the trough as the width of the ablation increases. The axes are marked before laser application, as typically done, and the laser irradiation appropriately delivered by the laser with diaphragm, ablatable mask, or scanning spot delivery system to create the elliptical ablation. For combined myopia and

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astigmatism, the dimensions of the major and minor axes of the ellipse and the depth of the ablation are calculated on the basis of the refractive error to be corrected.

Fig.17 demonstrates the corresponding case for correction of keratectomy exposing the bed. The laser energy is applied to leave a central projection, as in hyperopia correction, but surrounded by an elliptical ablated zone. The major and minor axes of the ellipse, and the height T3 and width D5 of the central projection are calculated from the components of the patient's refractive error.

Figs.18-19 demonstrate the operation of corneal intrastromal cavitation for the correction of refractive errors. The principle is to ablate or destroy a volumetric portion of tissue 210 from within the cornea 4 of such calculated shape such that once the optical breakdown products have been absorbed, the anterior corneal surface 6 is displaced posteriorly to close the potential space formed. This results in a new, desired anterior curvature calculated to eliminate the patient's problem. The shape of the volume to be ablated 210 is obviously related to the desired change in anterior curvature and the calculations for this type of procedure are well known.

The process for the correction of myopia is described. The scanning beam of the ultrashort pulsed laser using a wavelength

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transmissive by the cornea is localized to potential spherical surface 212 using any one of several methods. The preferred embodiment uses applanation contact of the cornea to identify the anterior surface of the cornea. The focus of the laser, using computer control, is then known at any time, depending on the displacement of the spot from the initial reference point. Or, the potential surface 212, at a desired depth from the anterior surface can be found at any point using the corneal profile or topography and the desired depth 214. Such laser corneal systems have been described in commercial literature by Intelligent Surgical Lasers, Inc., of San Diego, and Phoenix Laser Systems, of San Francisco. They have also been described in patents no. 4,848,340, Bille and Brown, issued Jul. 18, 1989, 4,901,718, Bille and Brown, issued Feb. 20, 1990, and 5,098,426, Sklar et. al., issued Mar. 24, 1992. Using such a system, the computer program directs the laser beam spot to be scanned through the corneal tissue in the same patterns and for the same purposes as described above for the contact lens 78 type of delivery system. Once a start point has been established at a desired depth, ablation commences. Any ablation path for the scanning spot can be used, such as spiral, concentric circles, adjacent linear elations, etc. Ablation proceeds from posterior to anterior within the cornea to avoid absorption of the beam energy by plasma. Thus, the beam spot is always moving into unablated tissue.

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In one embodiment (as described in Fig.4), the cornea is applanated by a hard material, which may be flat or curved, with a radius of curvature somewhat greater than that of the cornea. This prevents the expanding plasma and fluid resulting from ablation from distorting and displacing the cornea anteriorly, which would make the actual relation of the location of the laser spot to the desired location in the tissue unknown, as the corneal tissue is constantly being distorted by expanding plasma bubbles formed by the ablation. Contact or applanation of the anterior cornea prevents this as the anterior cornea cannot be displaced outwardly because of the rigid applanating plate. Ablation proceeds until the volumetric shape desired 210 has been ablated. The cavity for correction of myopia is seen to be delimited by the intersection of two potential spherical surfaces of different radii. The central width of the cavity is the difference in sagitta between these two curves with optic zone diameter D9 (typically 3-6 mm). It can be seen that an infinite number of paired surfaces may be used to achieve the same sized cavity, with the determination of shape of one defining the second. The paired surfaces are symmetric with respect to the anterior corneal surface and are centered on the visual axis 33. It is most important that in this invention an ultrashort pulsed laser is used, as this allows for reduced energy in the laser beam to achieve breakdown. This allows the production of a well defined cavity, with smooth boundaries, and with reduced collateral damage to the adjacent corneal tissue, especially the delicate endothelium. Accuracy in this procedure is dependent on a cavity of exact shape.

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Following ablation and absorption of the breakdown products, the closure of the cavity is postulated to result in posterior displacement of the central anterior cornea. However, experience has shown that this may not be accomplished, because of the rigidity of Bowman's membrane in the anterior cornea which resists bending. It is apparent that to create a new and flatter anterior cornea, there must be lateral or radial displacement of the anterior cornea over the boundary of the ablation zone, because we now demand that a given arclength of anterior cornea assume a flatter curvature over the same diameter, which will cause wrinkling or frank failure to flatten. This has been common experience with keratomileusis in the past. Thus, to overcome this problem and allow the cavitation procedure to work, the invention provides a relaxation incision 220. The purpose is to free and isolate the anterior cornea within the surgical zone from that more peripheral, thereby allowing the central portion 222 to displace itself as required, as is done in keratomileusis. This is accomplished as follows in the preferred embodiment. The laser spot 58 is scanned from the lateral edge 224 of the completed ablation zone of diameter D9 more peripherally to create a new annular surface with a radius similar to that of the anterior cornea until diameter D10 is reached. Thus, in Fig.19, we see ablation zone 224, surrounded by a plane of annular shape 226 with width 228. Upon reaching diameter D10, the spot is then scanned outward along path 230, until it exits the corneal surface. What has now been produced is a freely

isolated corneal lamellar disc, free to assume a new shape
without any impediment, since all attachment has been severed.
This is very similar to a typical keratomileusis end result.
The actual shape of path 230 can assume any desired shape, and
only one has been described. The purpose for moving
peripherally to D10 rather than scanning the spot directly
toward the surface at radius D9/2 is to prevent optical
symptoms, which can result when the anterior cornea is incised
at too small a distance from the visual axis. However, D10 may
equal D9 if desired.

An alternative relaxation incision is made as follows. Rather
than join the ablation cavity directly to the penetration at
the surface via path 220, it may be efficacious to simply
delimit the central anterior cornea with a circular incision at
some desired diameter equal to or beyond D9. Thus, the
scanning would produce an ablation along path 226, to some
desired depth into the cornea, but made from posterior to
anterior. This may allow the central cornea, in some cases,
enough freedom to equilibrate without actually separating
completely the lamellar disc. This may prevent gross undesired
movement or frank loss of the central portion, and eliminate
the need for any sutures.

Figs. 20-24 demonstrate the use of an ultrashort pulsed laser
for making various incisional patterns. Such incisions have
various uses, such as for performing radial, transverse, or

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arcuate keratectomy for the correction of myopia and astigmatism. If used in a circumferential pattern, they can be used to cut through or trephine the cornea (laser trephine) for corneal transplantation. In all the incisional patterns to be described, an ultrashort pulsed laser operating in the transmissive part of the electromagnetic spectrum with respect to the cornea is employed.

Fig.20 demonstrates the use of the laser in corneal transplantation (penetrating keratoplasty). The object is to allow the surgeon the ability of cutting precisely a partial diameter, full thickness corneal button 232 to transplant from the donor to the host, or recipient. Typically, the walls 234 of the incision are vertical, or parallel to the visual axis 33. This provides a button whose walls are a portion of a cylinder. Also, the transplant button is typically round, as this facilitates use of mechanical trephines. In this invention, we provide for a transplant button and host opening of any shape with walls at any angle.

In Fig.21 an elevation in section of the cornea is shown along with a central corneal button having been removed by the laser. The typical cornea 4 is 12-13 mm in diameter, and the typical button removed 232 is 7-9 mm in diameter. In this case the walls of the button and bed are vertical or cylindrical. The trephination is usually centered on the visual axis 33. Fig.20

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is a front view of Fig.21 and demonstrates the circularity of the margin 234 of the button 232 removed from the peripheral cornea 4.

Fig.22 demonstrates the operation of the laser in penetrating keratoplasty. The means of delivering the laser beam to the cornea have been described above. The laser beam spot of selected desired diameter is first focussed just posterior or just within the cornea 4, as desired by the given surgeon. Here it is shown just at the posterior margin 240 of the cornea. Then, the energy is delivered while scanning the laser spot such that the dotted path 242 through the cornea 4 is traversed, thereby producing a complete circular incision through the depth of the cornea. In Fig.20 it is seen that the beam spot 58 is scanned in a circular pattern 234. Following transection of the anterior cornea, the button 232 is easily removed by the surgeon. Both the donor button and the recipient host opening are cut in the same fashion, though the diameter of the donor button is typically greater than the host opening.

Under computer control, as previously described, the wall of the incision can take any shape. The delivery system simply scans such that any wall pattern is created, such as conical, and at any desired angle. Also, the shape in frontal projection can be made to vary from circular. For example, an elliptical opening can be created. Also, to correct

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astigmatism, the shape of the donor button and host opening can be different. For example, one may be circular and the other elliptical. Or, both elliptical with different major and minor radii. When inserting a donor of elliptical shape into a host opening of circular shape, for example, astigmatism or toricity of the anterior corneal surface will be induced. If the patient already had astigmatism, this operation would correct it.

Fig.23 is used to demonstrate the use of the laser in making various incisions or excisions for correcting refractive errors such as myopia and astigmatism. In this discussion, only several commonly used patterns are described, and it is obvious that any kind of incision may be made, other than the examples given. Incisions may be made as a penetrating incision, in which case the incision begins deep in the cornea and exits by penetrating the anterior corneal surface (solid lines), or they can be made totally intrastromally or within the cornea (dashed lines), in which case they do not penetrate the anterior cornea. Incisions depicted are penetrating 244 and intrastromal 246 radial incisions for correction of myopia, penetrating 248 and intrastromal 250 arcuate incisions and penetrating 252 and intrastromal 254 transverse incisions for the correction of astigmatism. Often, incisions for correcting myopia are combined with incisions for correcting astigmatism.

Fig.24 demonstrates, in an elevation in section of the cornea, radial intrastromal 262 and penetrating 264 incisions. In

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incisional techniques, the ablations are typically some distance from the visual axis 33 to prevent subjective visual symptoms, and often more than one is made in a symmetric fashion. The distance between the central most extent of the incisions is called the optic zone, here shown as D11. Incision 262 can be seen to be totally localized within the cornea, whereas incision 264 is seen to penetrate anteriorly. It is seen that the incisions are made deeply in the cornea, but not to its posterior surface, which is to be avoided in these techniques. Thus a layer of cornea 266 is left without incision at the end of surgery. The surgeon may select the percentage depth of the incision, and thus calculate from the corneal thickness the depth of cut and thickness of the zone uncut. The surgeon also selects the pattern or shape of the incision, its lateral extent and the diameter Dx of the zone not operated within centrally. Following the programming of all these variables into the computer, the laser delivery system is activated. The laser beam spot is located to a desired start point within the cornea, as previously described, and each incision is sequentially executed by the laser while scanning the spot under computer control. The delivery system scans from posterior to anterior along the length of the incision until the thickness of the incision is completed, whether partial thickness or penetrating, in which case the spot is scanned out through the surface to ensure penetration.

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Fig.25 describes the procedure of iridotomy using the invention. Either type of delivery system previously described, contact lens or tracking system may be used. However, the preferred embodiment is as a slit lamp delivery system. Here, the surgeon uses a joy stick to control the beam spot. Energy level, spot size, delivery pattern, and ablation time are all controlled by the surgeon. The laser has a HeNe focussing beam 270 coaxial with the ablating beam 272, and the surgeon focuses the beams at the surface of the iris 274 of the eye. Ablation begins under the control of the surgeon and the computerized beam delivery system ablates a circular area of iris. Ablation in this case is carried out from anterior to posterior, as the iris is not transparent to the laser radiation. The laser beam spot is scanned posteriorly until a through and through perforation 276 has occurred. In another embodiment, the ablation, which proceeds from the anterior surface of the iris, can be controlled to prevent accidental exposure of the lens capsule 278 just behind the iris, by locking in the point of the anterior surface with respect to translation and having the computer ensure that ablation can only proceed a safe distance into the eye.

Fig.26 demonstrates the use of the laser for glaucoma filtration surgery. Here the procedures of trabeculoplasty, trabeculectomy and sclerostomy are described. To perform laser trabeculoplasty, a slit lamp delivery system is the preferred embodiment. The surgeon places a Goldmann contact lens 280 on

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the eye, which is standard practice, and fires the laser beam 282 onto a mirror 284 in the Goldmann lens 280 such that the laser spot 58 ablates a small spot of trabecular tissue, thereby deforming its contour and aiding in fluid outflow. The spot size, energy level, depth of ablation, etc., are all controlled by the surgeon.

Fig.26 also shows other filtering procedures to reduce intraocular pressure. A drainage channel 286 can be bored into the eye by a laser 288 from the limbal area until it reaches deep into the eye until fluid seeps out or until penetration. Alternatively, the drainage channel can be partial thickness and covered by a flap externally for safety. These procedures are well known and not described in detail. Lastly, the drainage channel can be made using the Goldmann lens, in which case it can be initiated inside the eye and carried outward for partial or complete penetration. In all glaucoma procedures, the HeNe focussing beam, etc. is used, but details are not shown as it has been described before.

Figs.27-28 demonstrate the performance of anterior capsulectomy (capsulorhexis) and posterior capsulectomy of the lens 289. In Fig.27, the left side demonstrates half an anterior capsule 290 opened by the invention, whereas the right side a capsulectomy 292 performed manually or with previous laser technology, should it be used for this application. This is accomplished with an ultrashort pulsed laser using a wavelength transmitted by the cornea. The purpose is to allow the surgeon to open the

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lens capsule with a smoothly contoured incision of desired shape and with minimal trauma to facilitate the cataract surgery to follow, or to allow an unimpeded path for light from the environment to the retina in post cataract patients with an opacified posterior capsule. The ability to open a lens capsule in a regular and controlled manner is of great importance. A smooth and regular opening in the anterior capsule prevents the complications of capsule tear or rupture, or difficulties in inserting the intraocular lens because of an inappropriately sized opening. Also, opening either capsule with the invention significantly reduces the acoustic shock waves within the eye and reduces the possibilities of retinal complications or damage to the prosthetic lens.

The operation is performed as follows. The focus of the laser beam spot is localized to the anterior lens capsule by direct visualization using a visible HeNe laser beam focussed to the same focal point as the ablating laser, as typically done, at distance D11/2 from the center of the anterior lens capsule 294. This defines the diameter of the capsulorhexis. Then, the surgeon displaces the HeNe positioning beam just posteriorly to the capsule at D11/2, or a selected distance can be programmed into the beam control computer, and photodisruption begins. The beam 296 is directed in a circular pattern, beginning posteriorly and translating anteriorly while following path 298, to ensure complete transection of the capsule. The cutting process can be totally computerized once

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the reference point on the capsule has been fixed, or the surgeon can terminate the process when the capsule has been visibly cut for 360 degrees. Typically, the surgeon will manually remove the freed central layer of capsule within the ablation boundary shortly thereafter, during cataract surgery.

For a posterior capsulectomy, the process is similar, except that D11 is significantly less, typically 1-3 mm. A posterior capsulectomy is performed to open an opacified posterior lens capsule in patients who have undergone cataract surgery, and whose opacified posterior capsule impedes the passage of light rays to the retina, decreasing vision. Also, the process of removing the posterior capsule is carried out done without anticipation of entering the eye. Thus, to remove the capsule central to the 360 degree circular ablation, the computer may direct a series of concentric circular ablations, or any other pattern to totally destroy the central area within the circular area of diameter D11, thus providing an unimpeded path for light from the environment to the retina.

Figs.29-30 demonstrate the principle of phacorefractive ablation. The purpose of this procedure is to modify the refractive power of the eye by altering the curvature, and hence refractive power, of the lens as opposed to modification of corneal refractive power by altering corneal curvature. Altering the shape of the cornea to produce refractive change is known to be accompanied by various subjective symptoms. It is established that a given degree of irregularity or

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abnormality in a refractive surface causes more symptoms if it is located further from the focal point of the eye. It has been established that such aberrations would be reduced if located at the position of the lens. Also, the capsule of the lens is pliable and will easily deform itself around the cortical lens substance with new curvature. The concept is to ablate some of the substance of the lens 299 of the eye in a non-traumatic fashion such that lens material is removed from under the anterior lens capsule 14 in a controlled fashion. The laser source is an ultrashort , pulsed laser, using a wavelength transmissive to the cornea and the lens. The laser is focussed within the lens itself, scanned in a pattern appropriate for the shape of the calculated ablation, and, by photodisruption, the lens material is ablated. Following absorbtion of the breakdown products, the anterior lens capsule is displaced to close the resulting potential space within the lens. This displacement is enhanced by the pressure vector 302 exerted on the capsule by the intraocular pressure, which is approximately 10-23 mm Hg. Although complete ablation in the surgical zone is preferred, it is possible that a change in the viscoelastic nature of the lens material may also allow for a surgically satisfactory result, although perhaps of lesser magnitude. It is most important that the anterior lens capsule 14 not be damaged in the process. Thus, the positioning and localization of the laser beam spot is critical. For this reason a safety zone of width 304 is thus left posterior to the anterior lens capsule 14. The laser beam may be localized with respect to

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the anterior lens capsule by using a HeNe laser which is arranged such that the focal point is identical to the ablating laser. The HeNe beam can be focused on the anterior lens capsule 14 and the zero position noted by the computer. Then the safety distance 304 is added to localize the laser focal spot posterior to the anterior lens capsule 14. Alternatively, since the distances between optical components of the eye can be known accurately by using ultrasound measurement, the laser beam can first be oriented to the front of the cornea by the contact lens delivery system. Then, the measured distance of the anterior lens capsule from the anterior corneal surface is programmed in along with the width of safety zone 306 before beginning the ablation. Ablation begins posteriorly and the laser spot is scanned in any of several patterns as previously described until the entire volume 299 has been ablated, thus terminating at the calculated safety distance. Ablation proceeds from posterior to anterior to avoid absorbtion of the beam energy by the plasma already formed. Initially, plasma or fluid is produced. The diameter D12 the ablation zone may be in the range of 3-7 mm., but not limited to this range. In addition, astigmatism, with or without myopia, can also be corrected by ablating a cylindric or toric pattern rather than a spherical one, as previously described. Also, hyperopia, with or without astigmatism is also correctable. In this case, the shape of the volume ablated is such that width 304 is minimal at the point where the visual axis intersects the lens and the ablation width increases as one moves radially from the

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center, or visual axis. Any pattern, aspheric or spheric, can be programmed into the computer to control the ablation geometry for a desired result.

Fig.31 demonstrates the use of the laser to cut vitreous bands or membranes. A vitreous membrane 20 is shown, lying close to the retina. The preferred embodiment is the slit lamp delivery system with HeNe focussing laser as previously described. The surgeon focuses the beam directly on the membrane, using the Goldmann type lens 280. With a foot or manual control, the beam 88 transmissive by the cornea, lens and vitreous, is applied to the membrane, and the surgeon uses a joy stick control to manually guide the beam through the membrane to achieve the desired cutting or ablation effect. The surgeon controls the energy, spot size, and laser beam burst time. The gentle femptosecond pulse width laser reduces acoustic shock and allows the surgeon to operate closer to the retina than with current technology.

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What is claimed is:

1.   A method for performing a lamellar keratectomy on tissue
of a cornea, whereby a partial thickness lamellar disc of
tissue is freed from the surrounding corneal tissue, said
method comprising the steps of:

   generating a pulsed laser beam, said beam having a
   duration of an ultrashort pulse width, and having a
   wavelength in a part of the electromagnetic spectrum that
   is transmitted by the cornea;

   directing the laser beam to a selected start position
   within the cornea;

   selecting a power density for said laser beam;

   scanning a laser spot through the corneal tissue in a
   predetermined manner such that a disc to be remove is
   outlined and freed from the remaining cornea by ablation
   of tissue along a path scanned.

2.   A method according to Claim 1 whereby an edge shape of the
resected lamellar disc is varied as desired for specific
applications by altering the path of the scanning spot as it
traverses from within the cornea to finally exit the cornea
anteriorly.

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3.   A method for performing a photorefractive lamellar keratectomy on corneal tissue, whereby a partial thickness lamellar disc of tissue is removed intact from an anterior cornea, such lamellar disc being of varying thickness such that it is a lens with refractive power, the removal of which leaves behind a new anterior corneal surface of refractive power different than prior to the keratectomy, said method comprising the steps of:

generating a pulsed laser beam, having a duration of ultrashort pulse width, and having a frequency in a portion of the magnetic spectrum that is transmitted by the cornea;

directing the laser beam to a selected start position with the cornea;

selecting a power density for said laser beam;

scanning a laser spot through the corneal tissue in a predetermined manner such that the disc to be removed is outlined and isolated from the remaining cornea by ablation of tissue along a path scanned.

4.   A method according to Claim 3 where the resected lamellar lens is a convex lens for correction of myopia.

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5.   A method according to Claim 3 in which the resected lamellar lens is concave for correction of hyperopia.

6.   A method according to Claim 3 where the resected lens is aspheric in the sense that there is a peripheral zone of varying curvature, comprising a means for improving wound healing and surgical result.

7.   A method according Claim 1 wherein the pulse width of the laser beam is in the range of 10-400 fs.

8.   A method according to Claim 3 in which the resected lamellar lens is an aspheric lens for correction of astigmatism, regular and irregular, and spherical aberration.

9.   A method according Claim 3 wherein the pulse width of the laser beam is in the range of 10-400 fs.

10.   A method according to Claim 3 whereby an edge shape of the resected lamellar disc may be varied as desired for specific applications by altering the path of th scanned spot as it traverses from within the cornea to finally exit the cornea anteriorty.

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11. A method for altering the refractive power of the eye to allow for the correction of various optical errors such as myopia, hyperopia, astigmatism, combinations thereof, irregular astigmatism, spherical aberration, etc., comprising:

generating an ultrashort pulsed laser beam with wavelength in the part of the electromagnetic spectrum that is transmitted by the cornea and the lens;

directing the laser beam to a selected start position within the lens substance;

selecting a power density for said laser beam;

scanning the laser spot of selected power density through the lens tissue along a predetermined path of desired shaped, and ablating from posterior to anterior until a volumetric mass of predetermined shape, calculated to correct the optical problem, has been ablated by photodisruption of the lens material.

12. A method according to Claim 11 wherein the pulse width of the laser beam is in the range of 10-400 fs.

13. A method as stated in Claim 11 whereby the power density of the laser beam is controlled by varying the pulse width.

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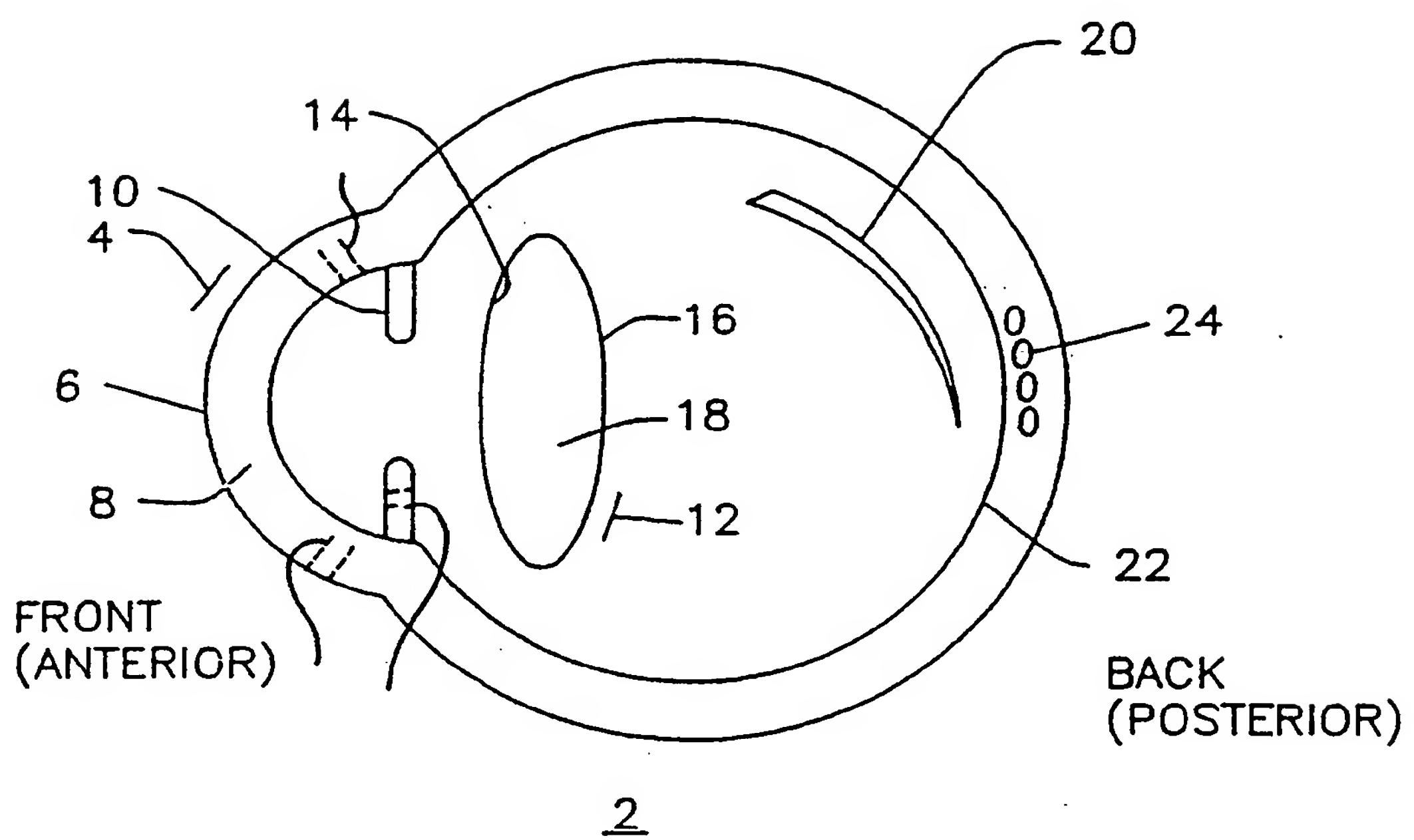
FIG. 1

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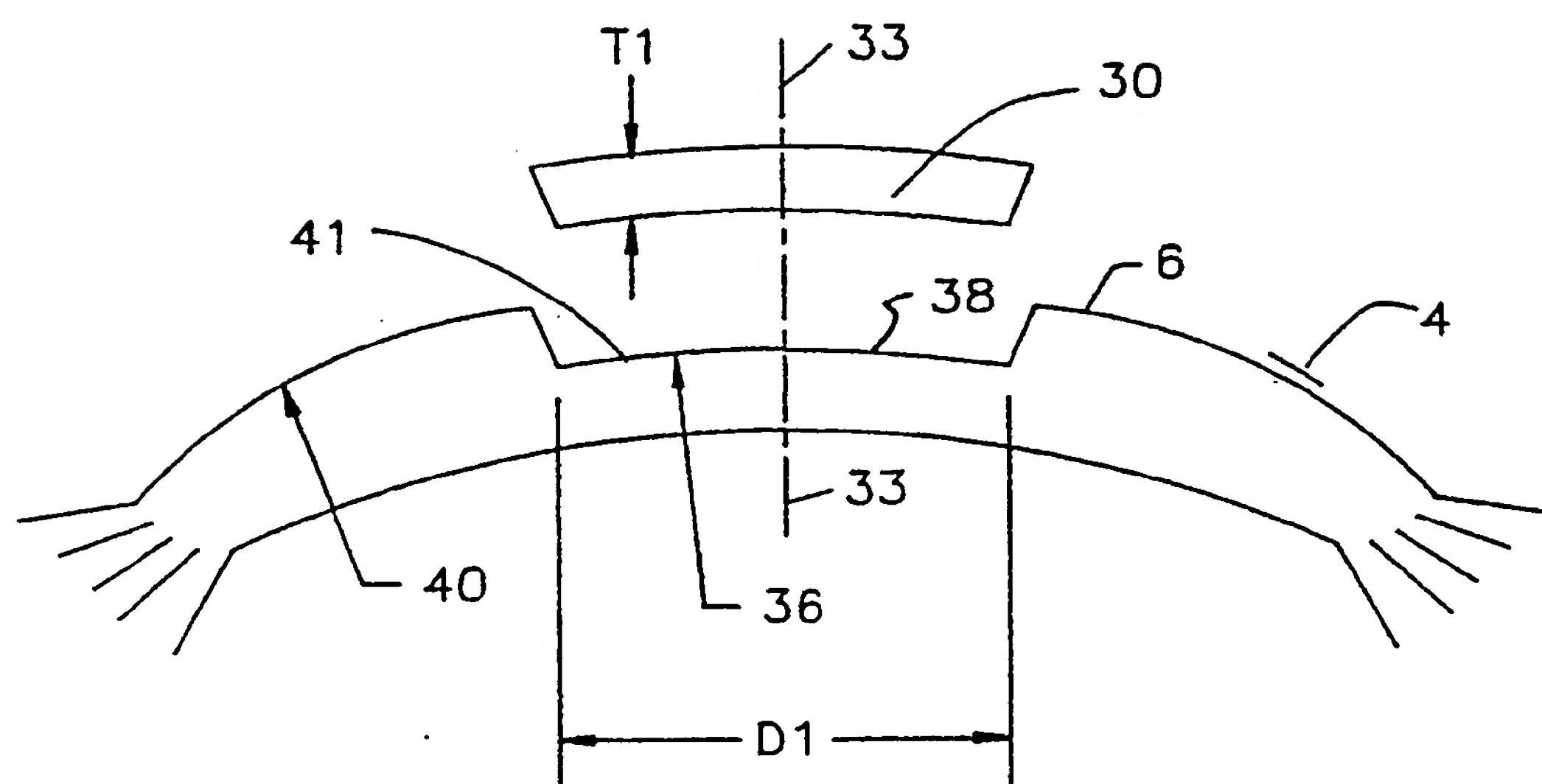
FIG. 2

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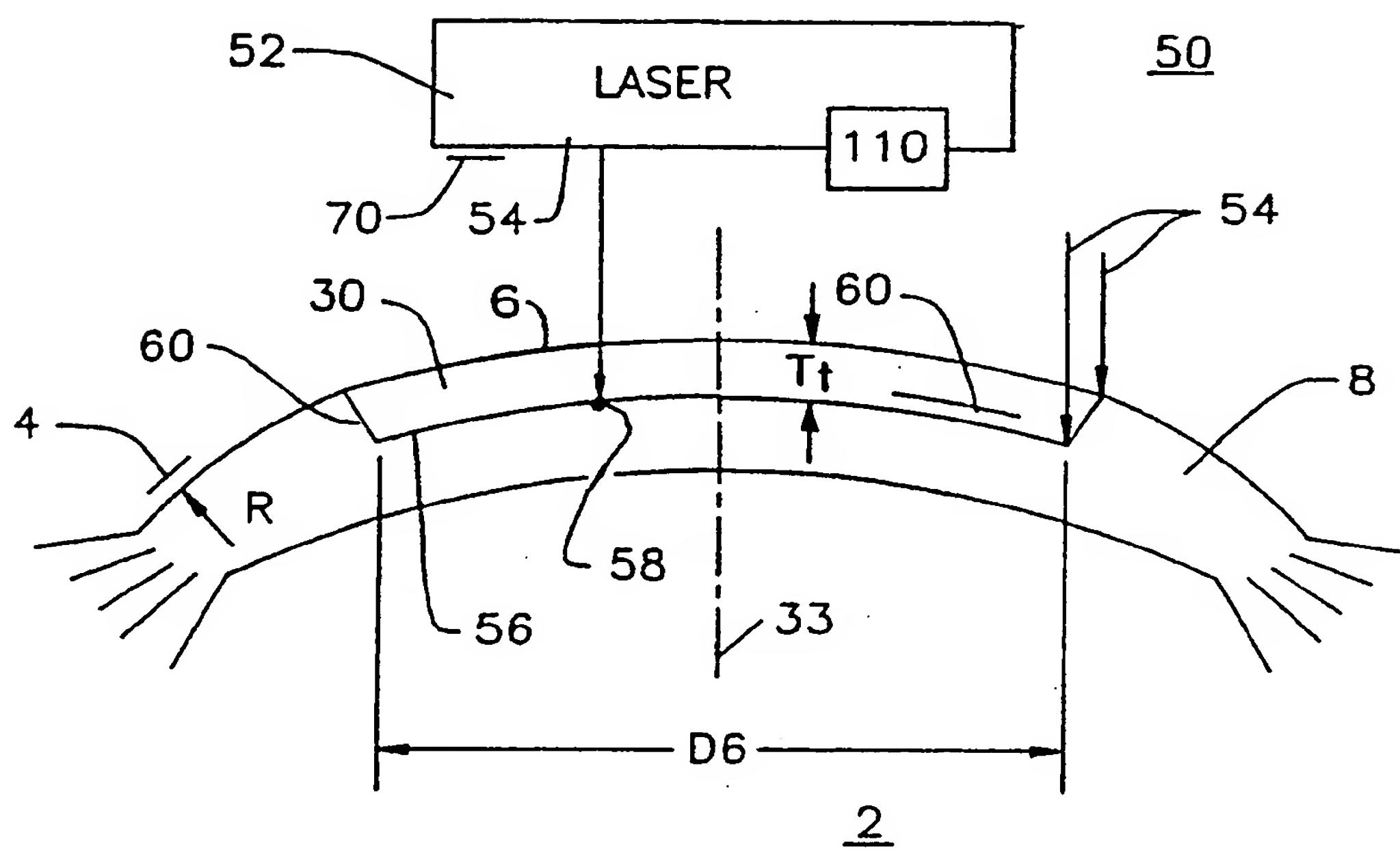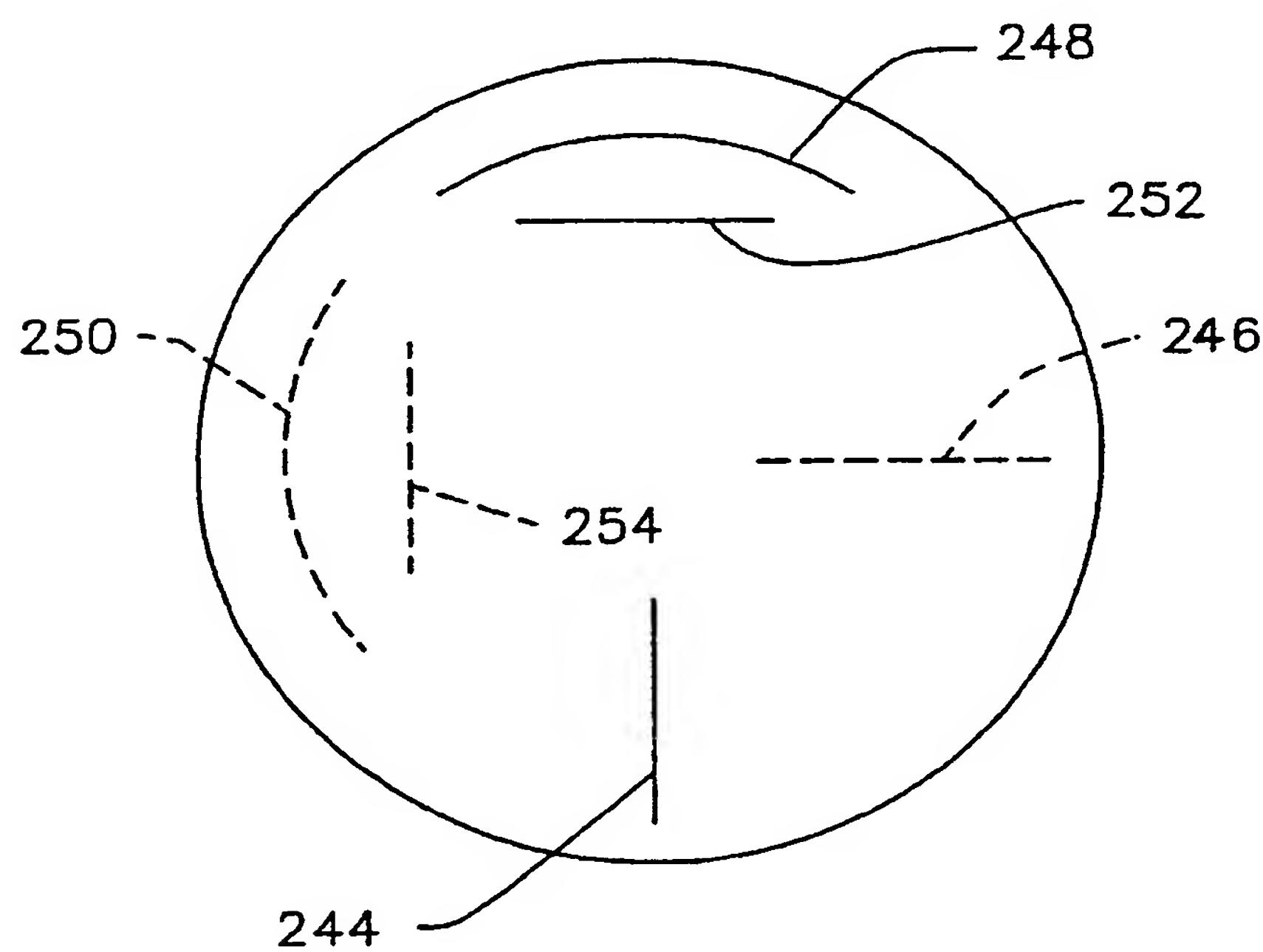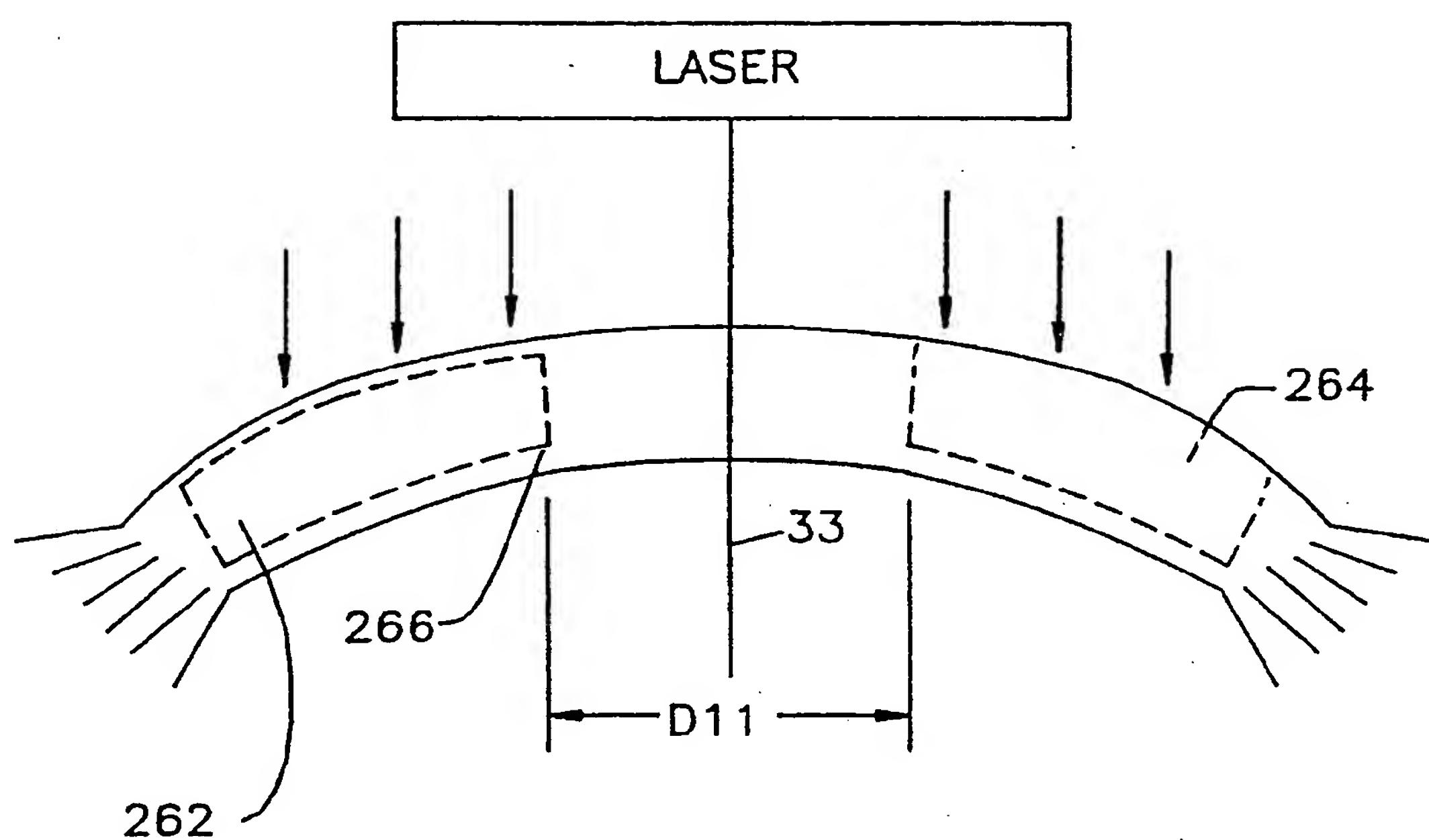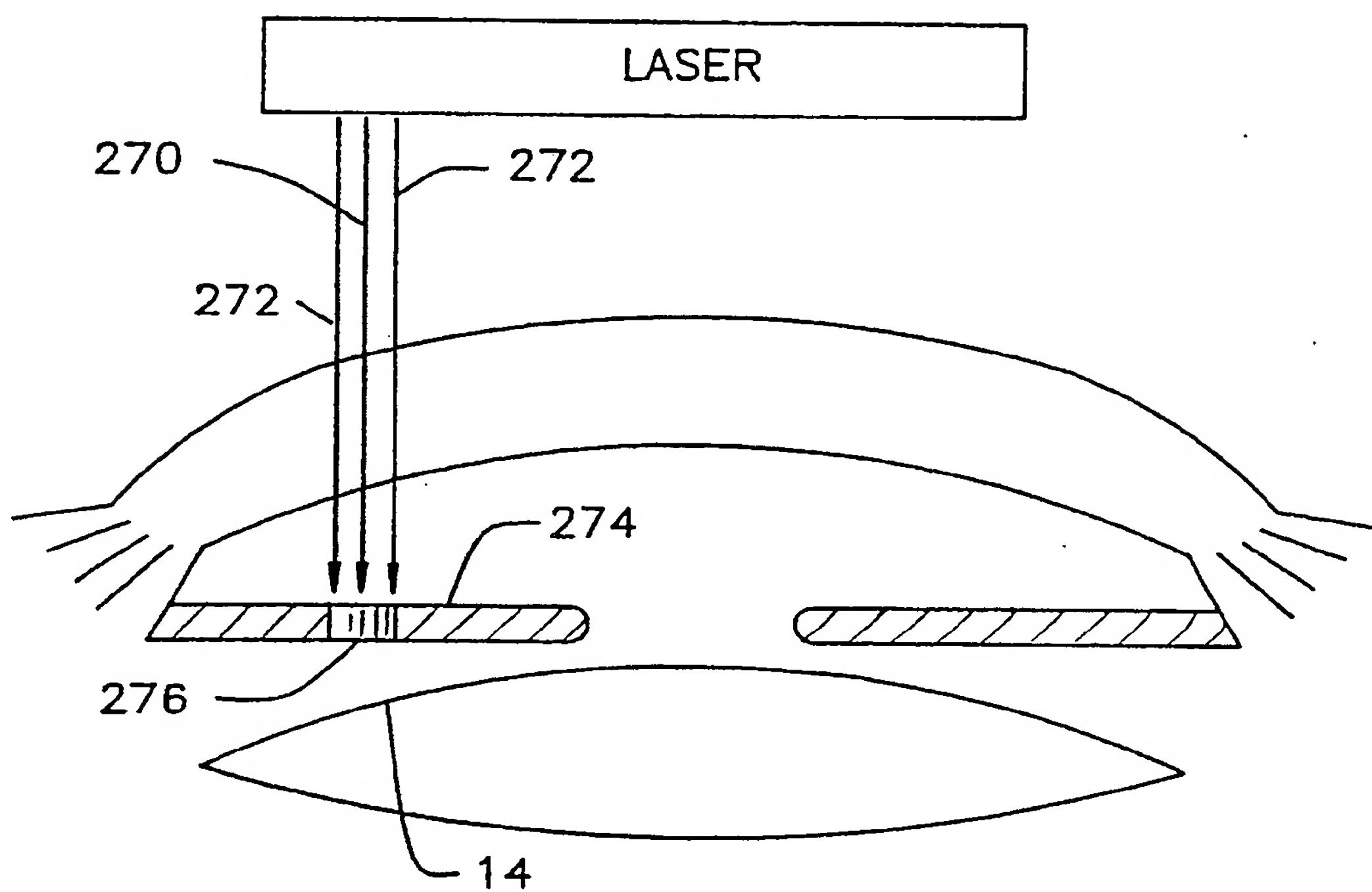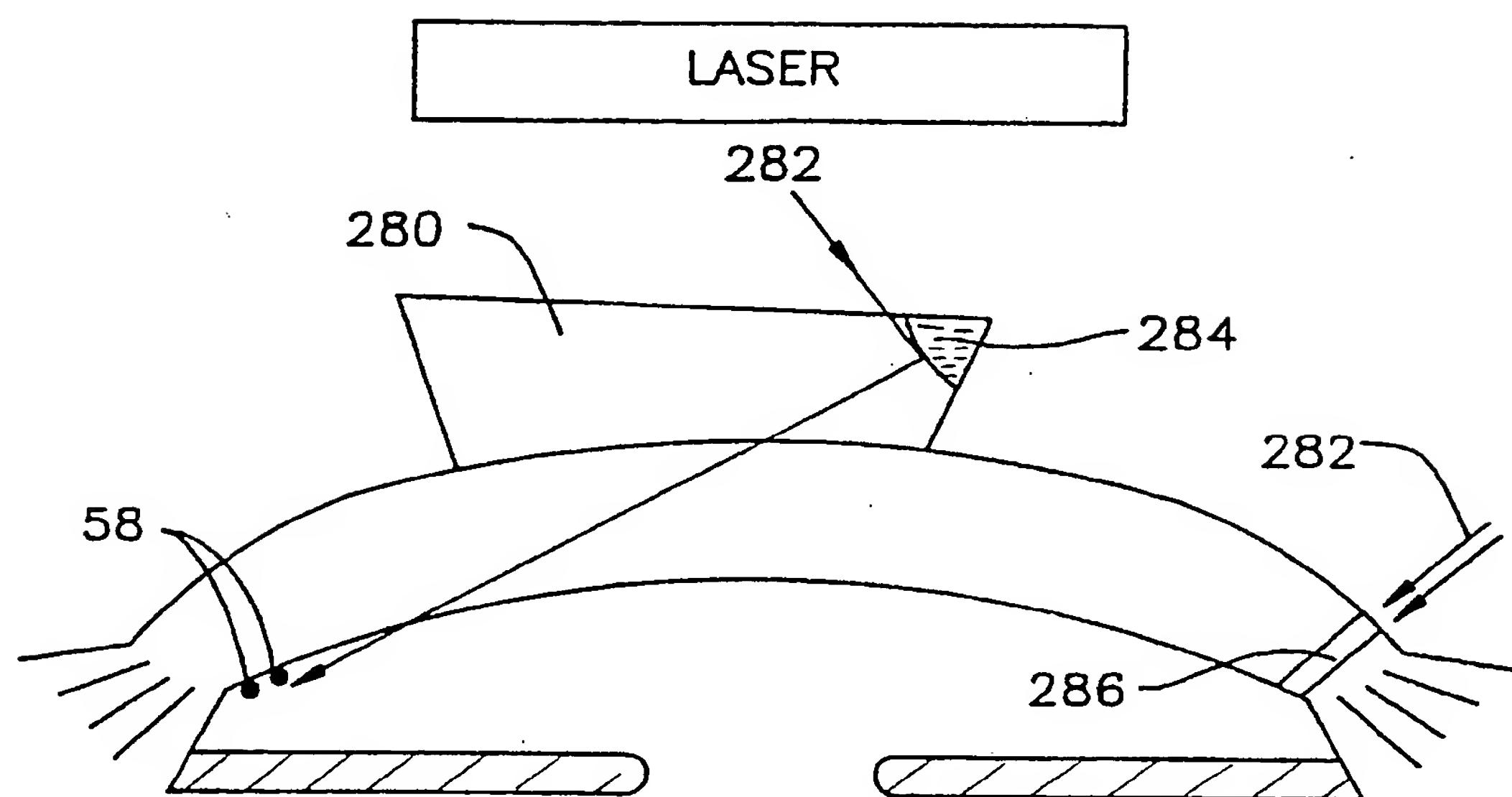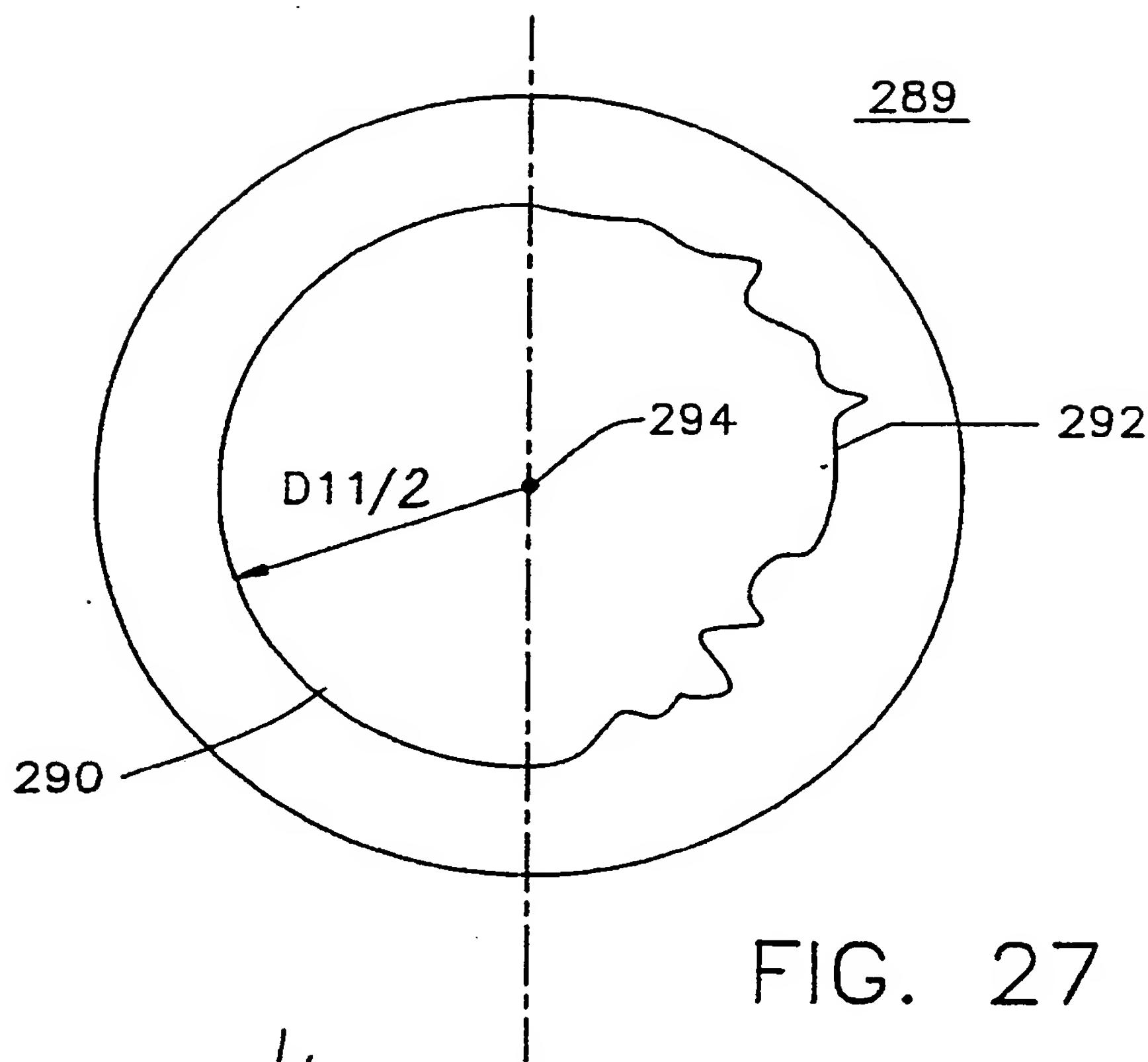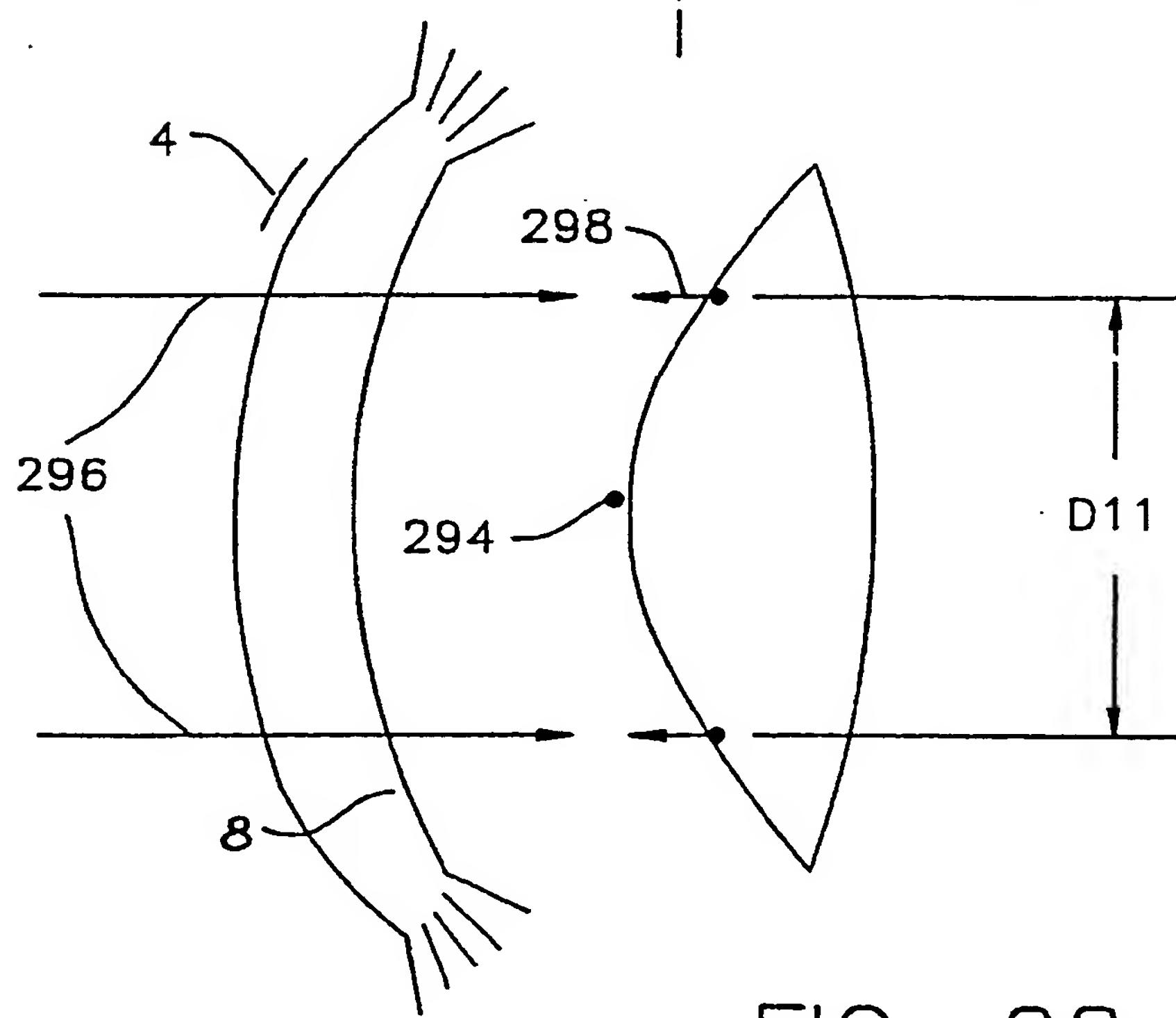
FIG. 3

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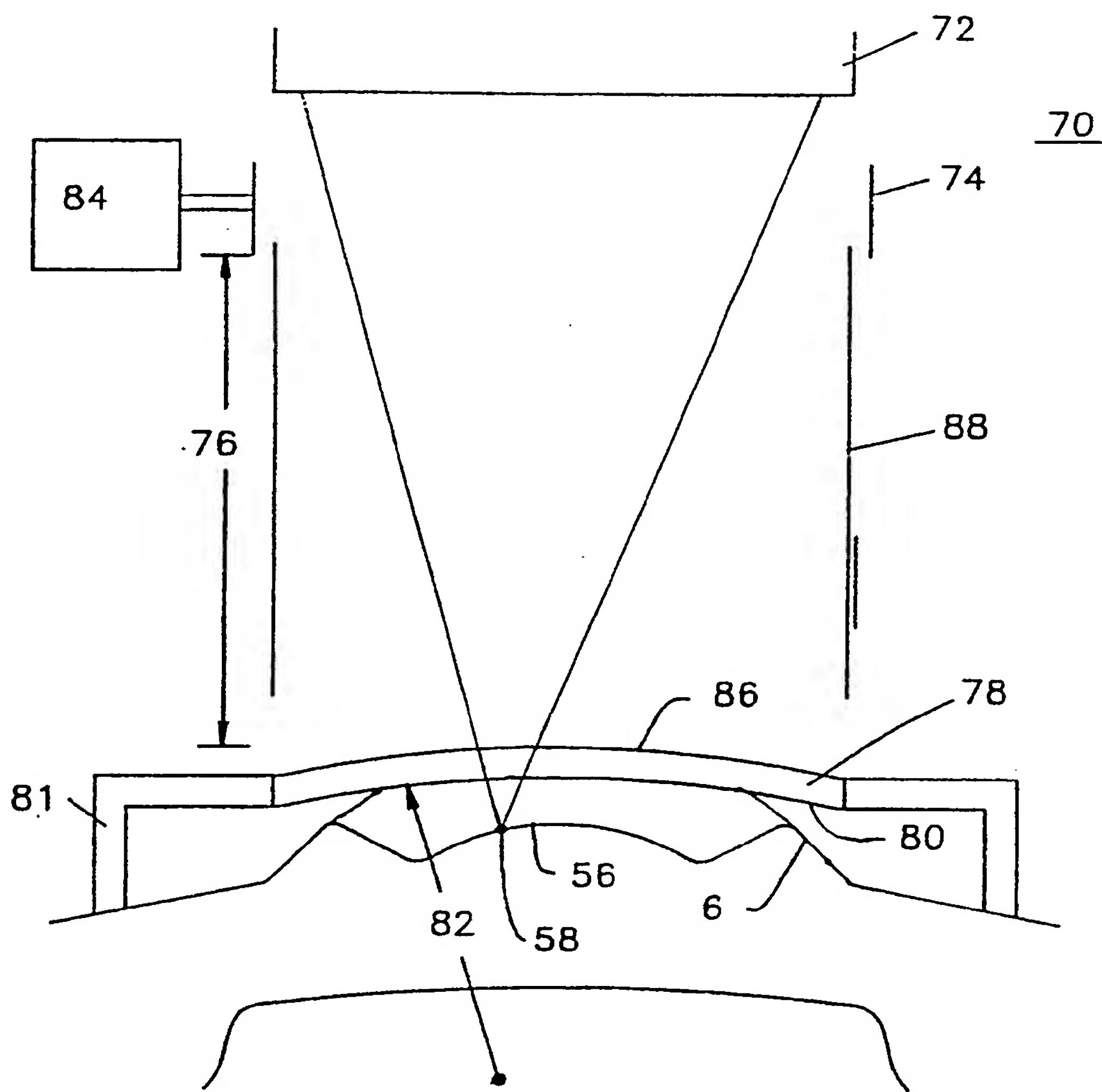
FIG. 4

SUBSTITUTE SHEET (RULE 26)
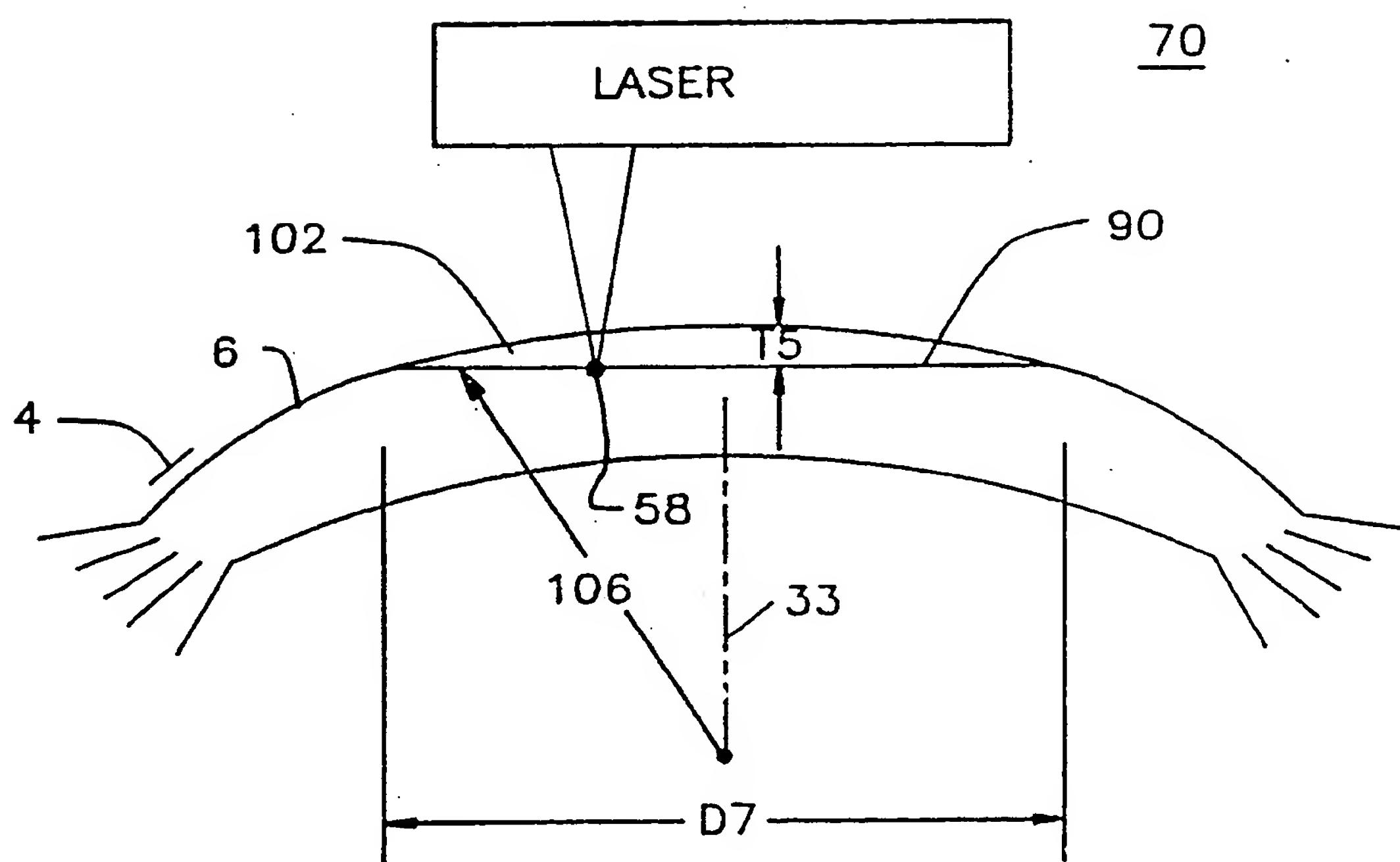
FIG. 5

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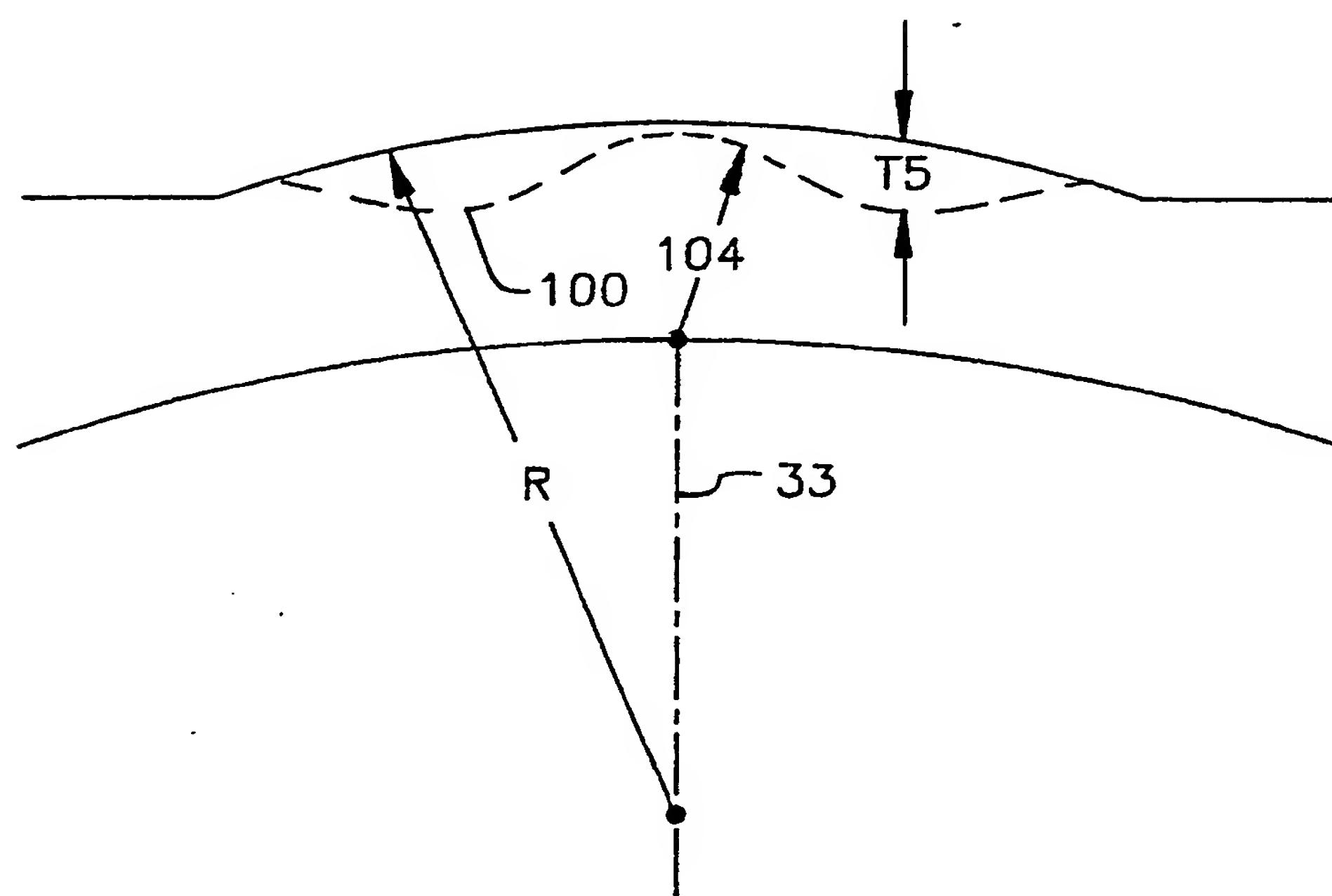
FIG. 6

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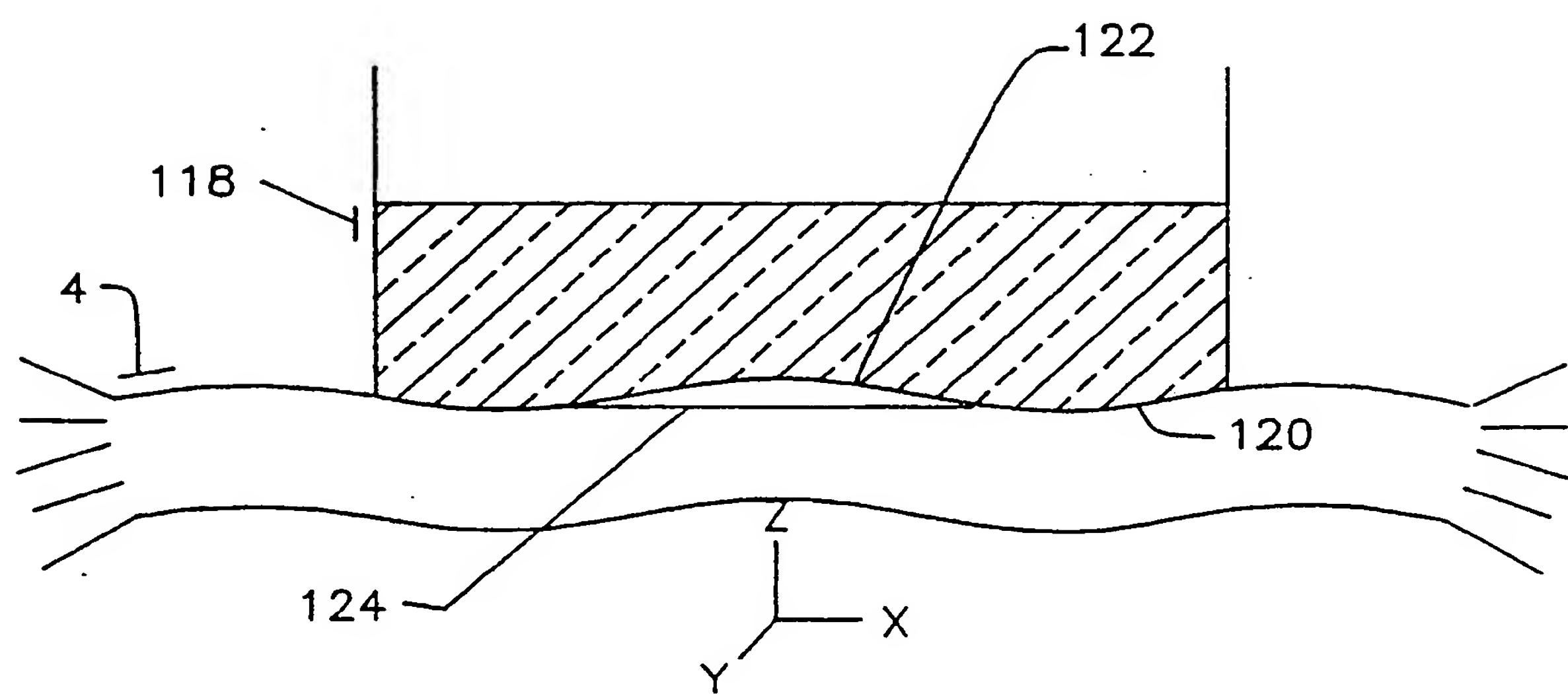
FIG. 7

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FIG. 8

FIG. 9

LASER

136

30   134   132

33   133

FIG. 10

140

T2   T1

D2

FIG. 11

142   30

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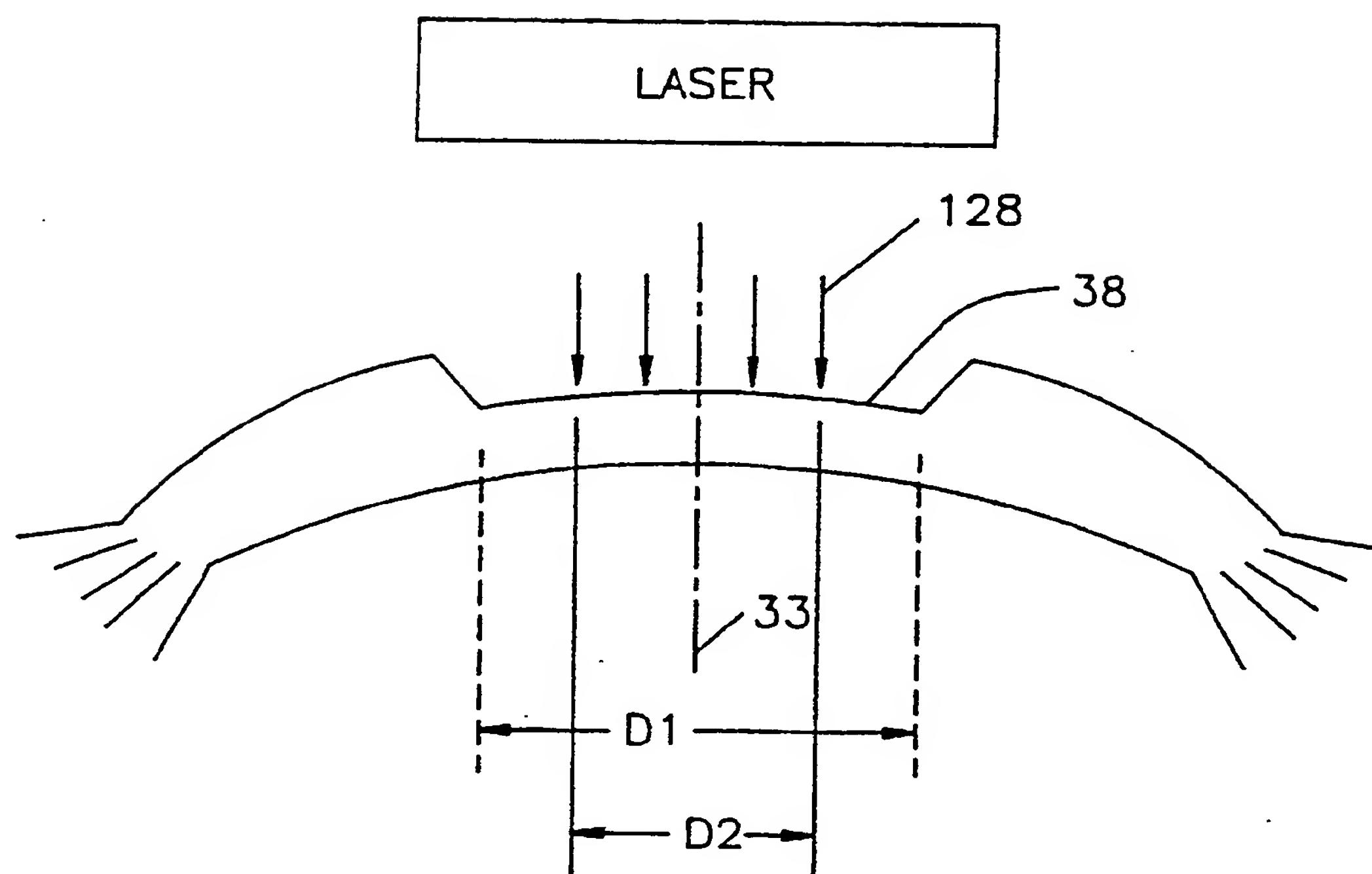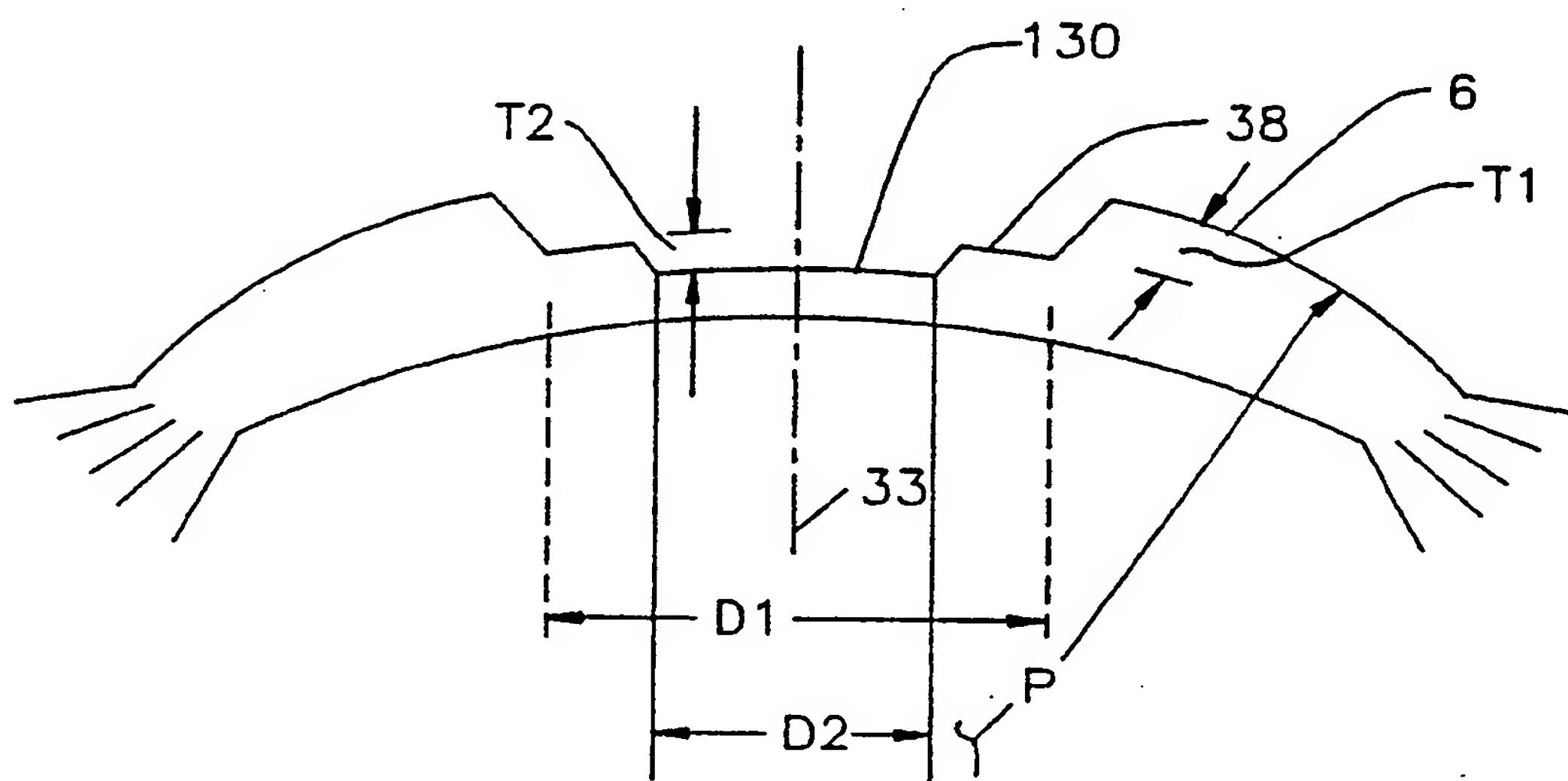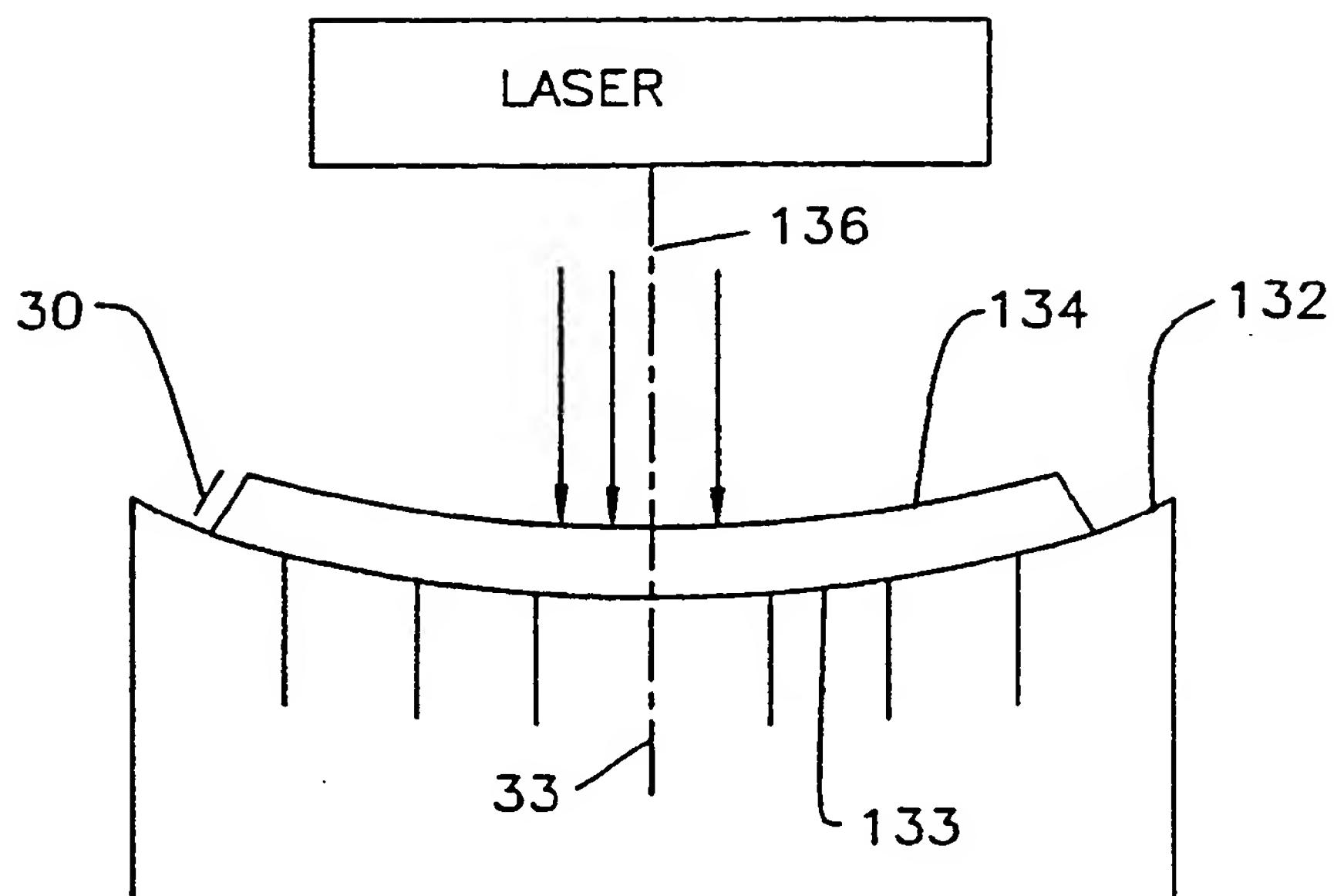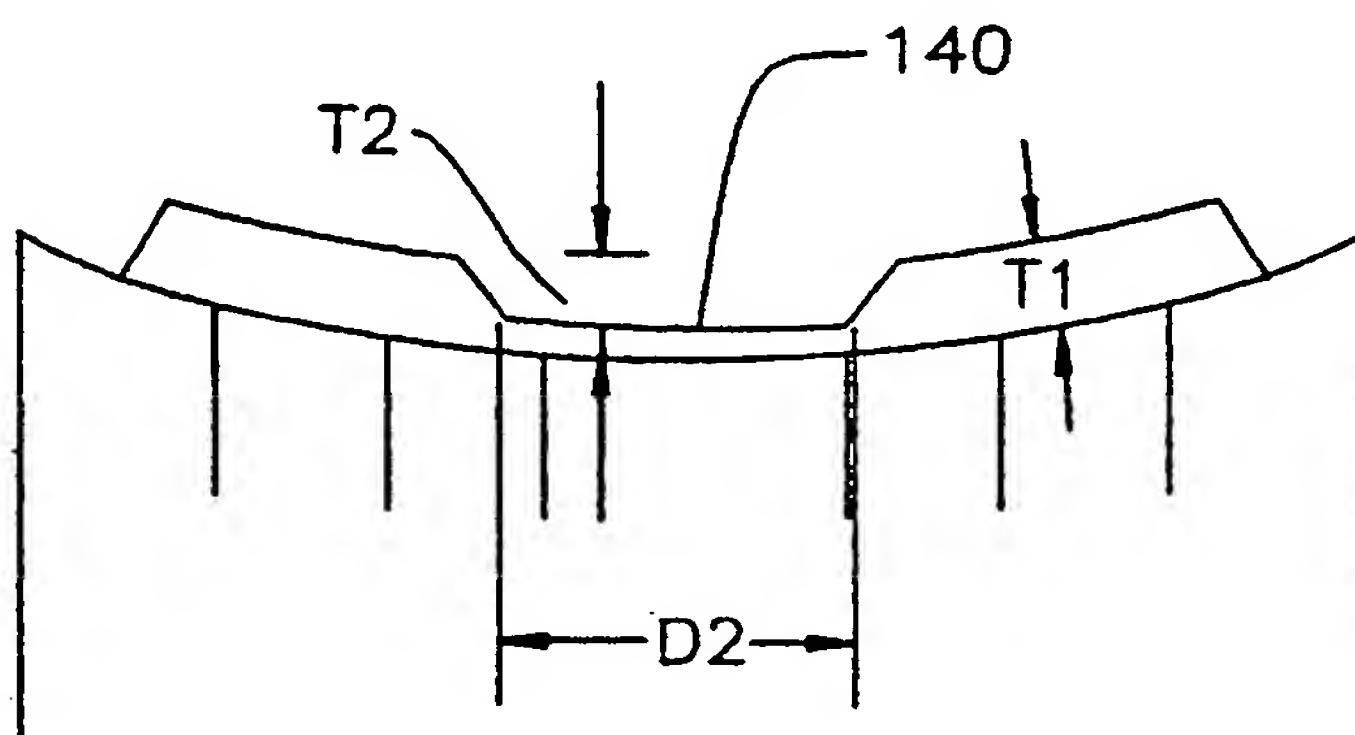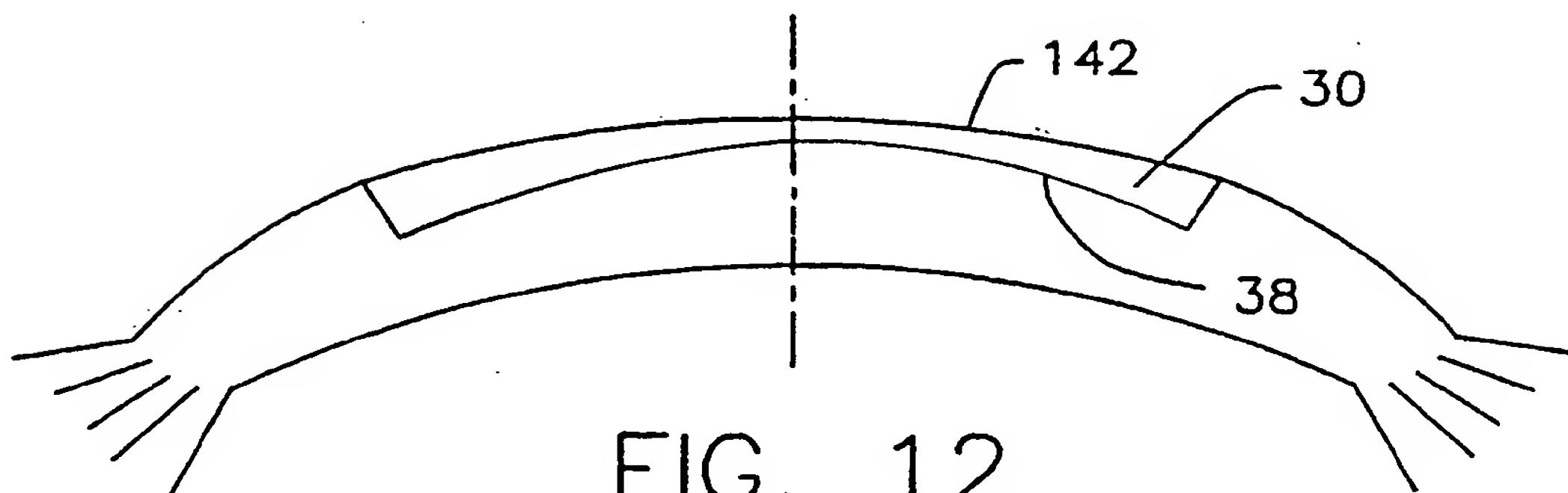
FIG. 12

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FIG. 13

FIG. 14

FIG. 15

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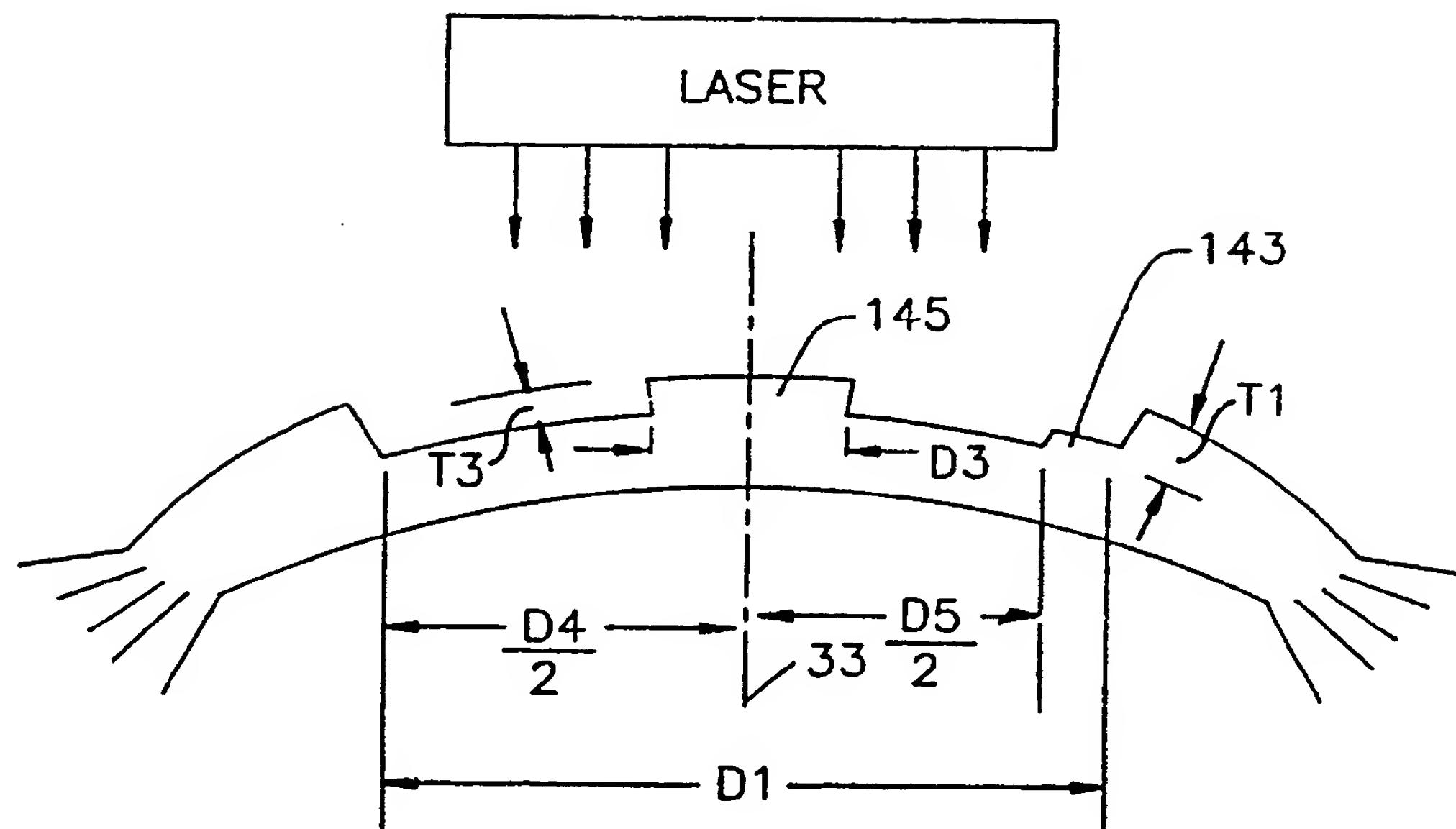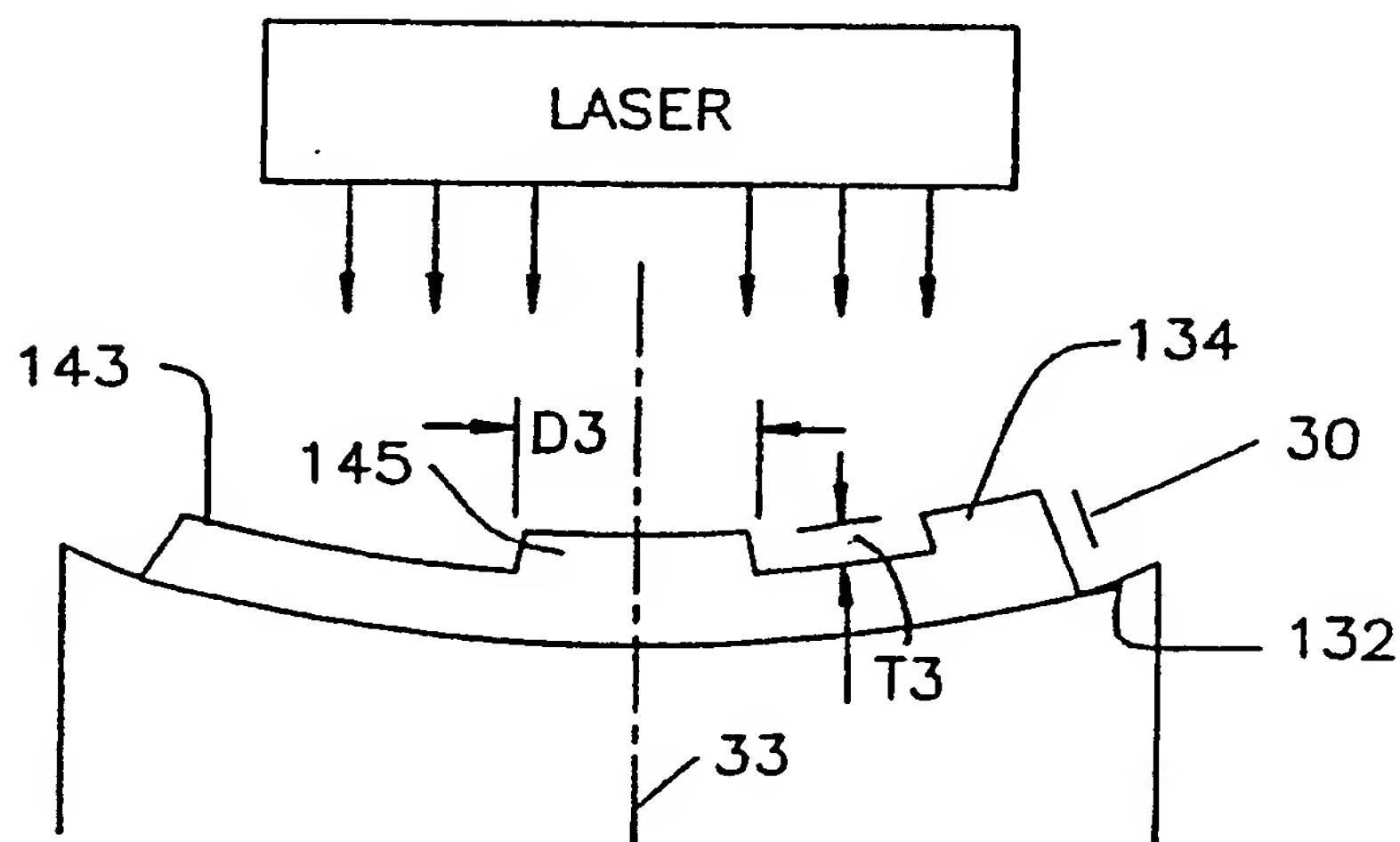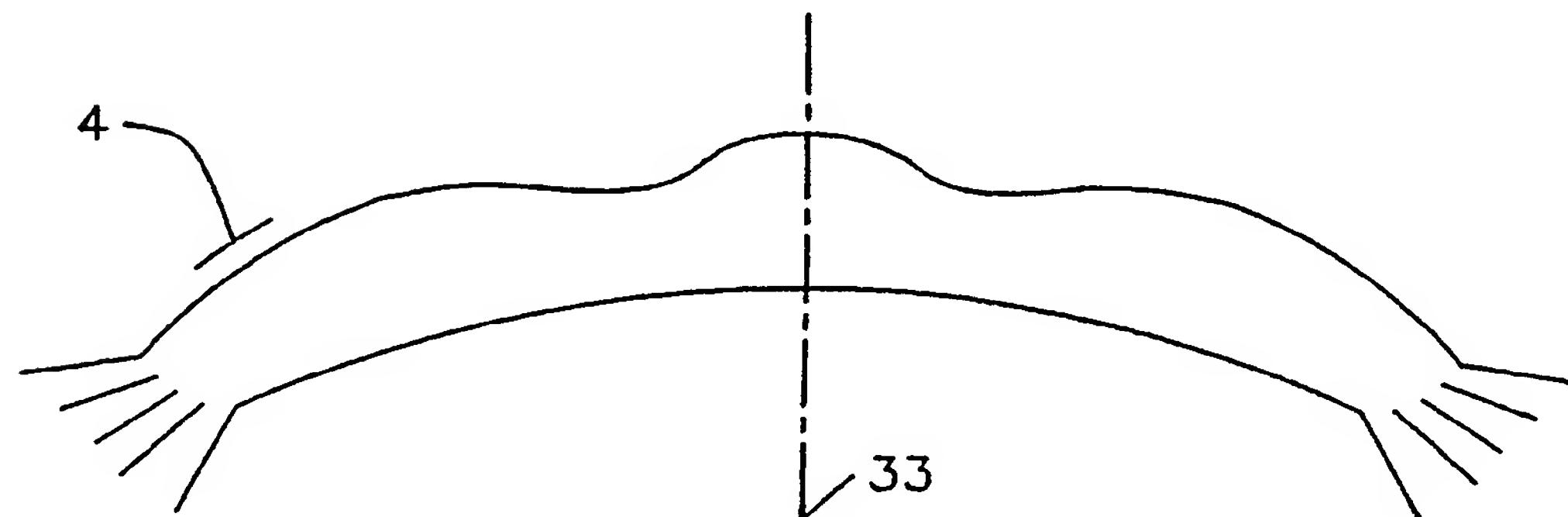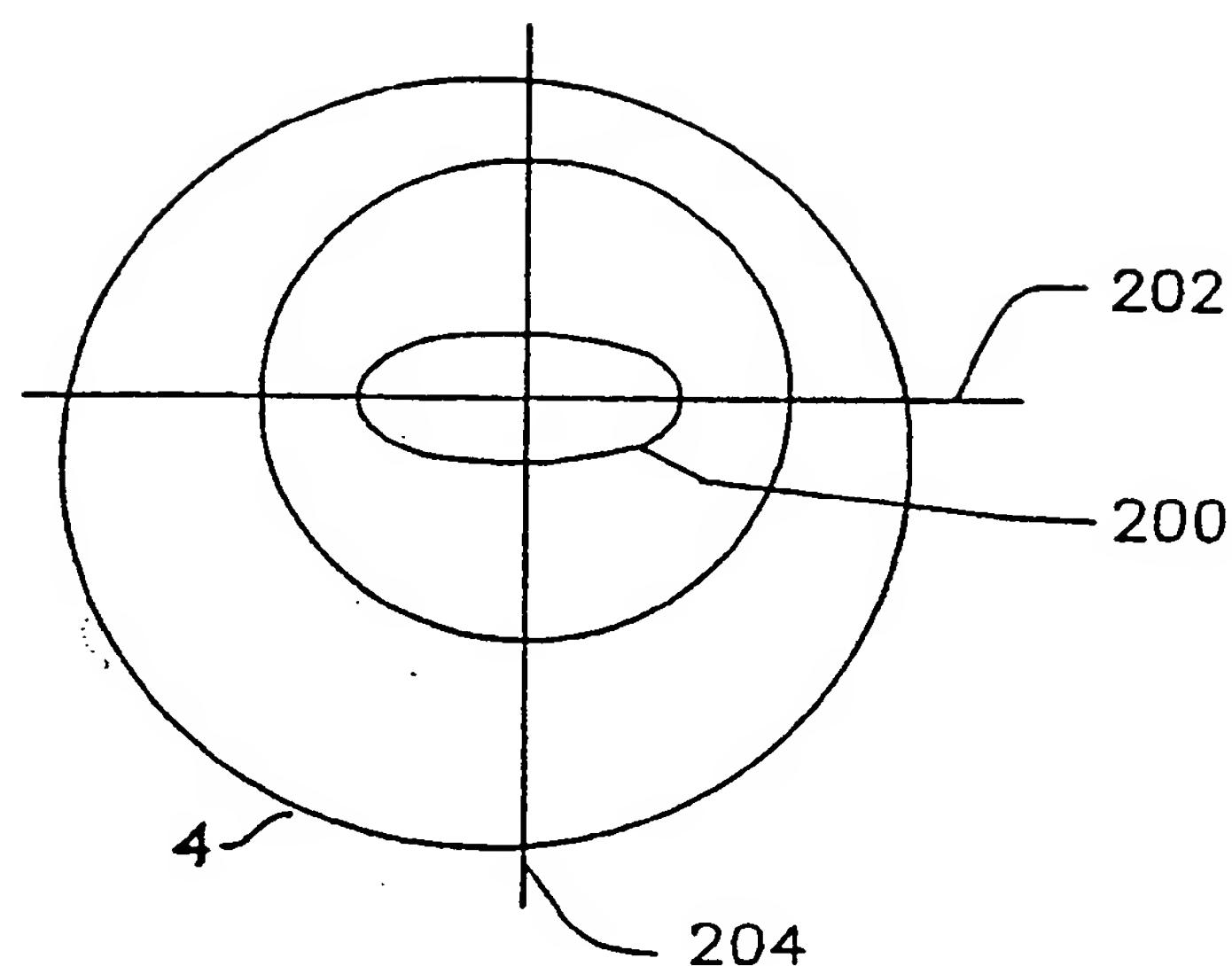
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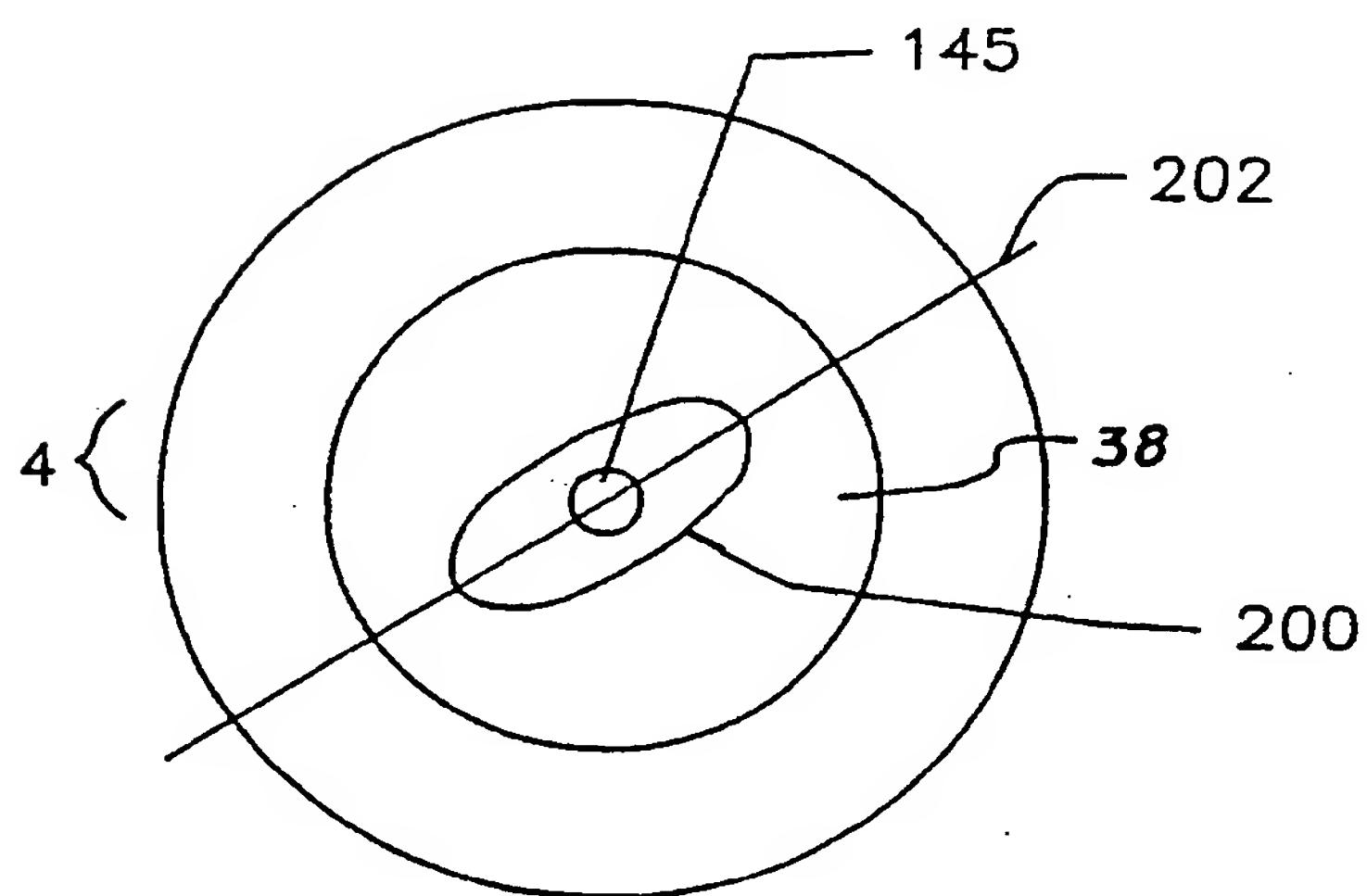
FIG. 17

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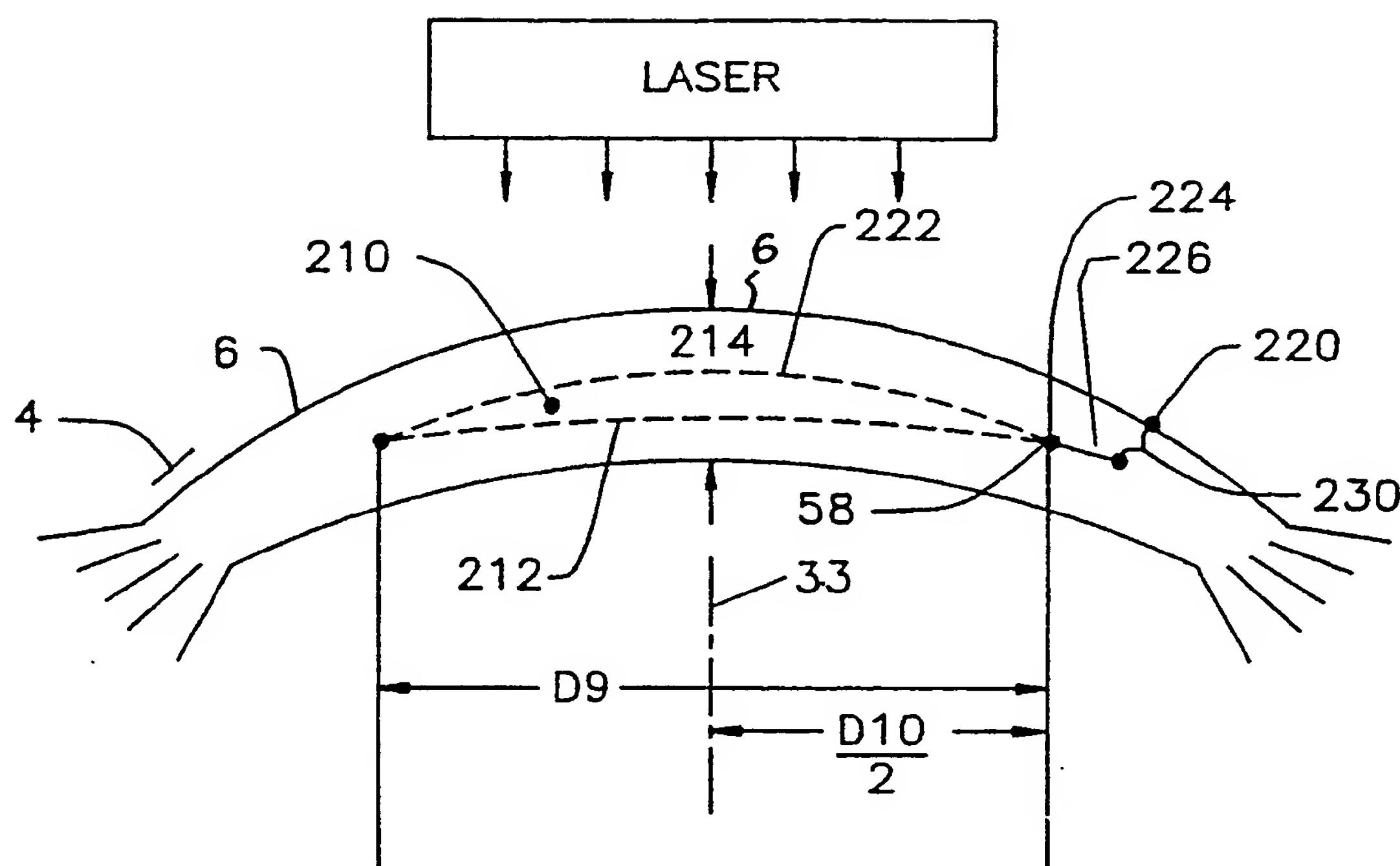
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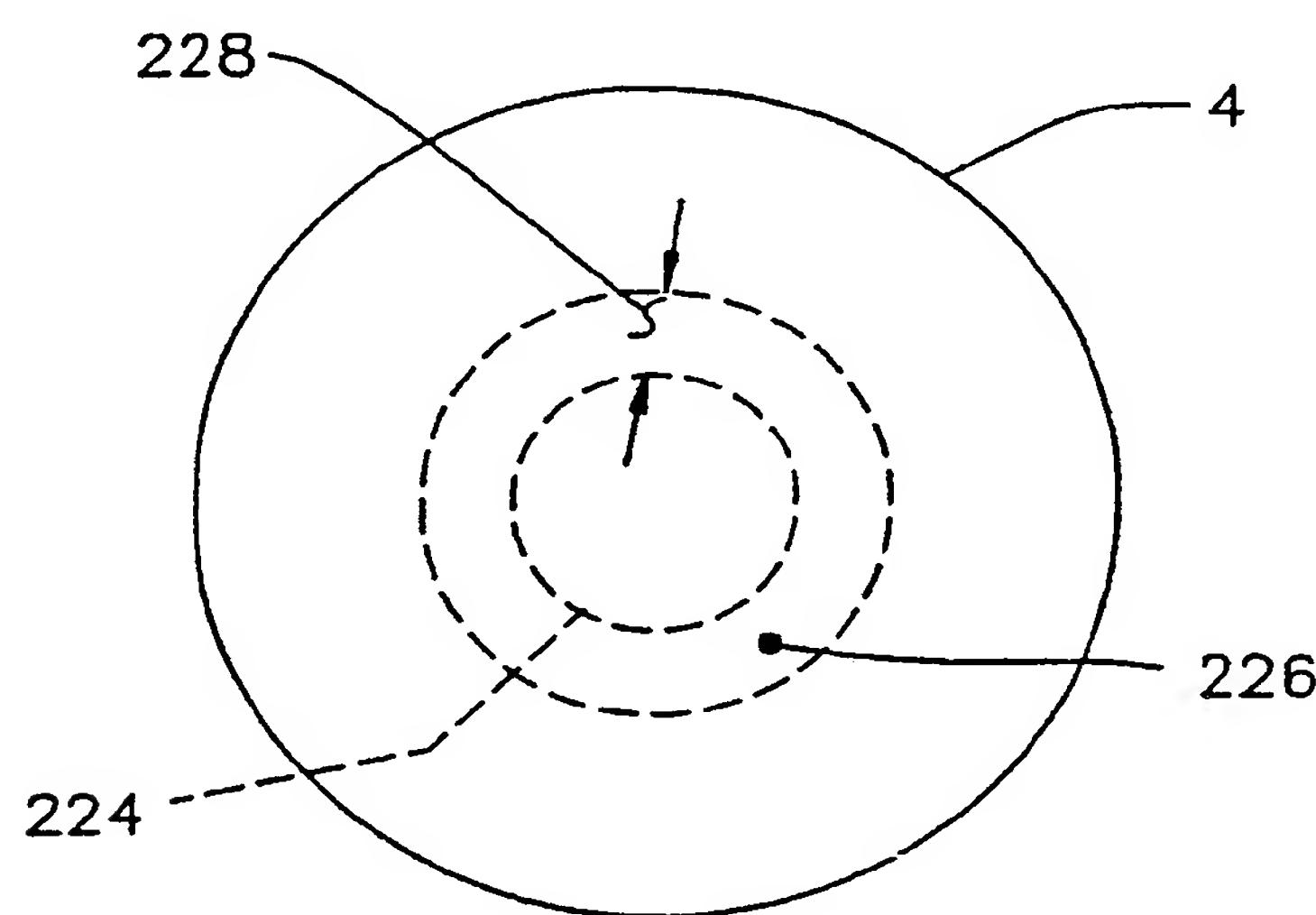
FIG. 19
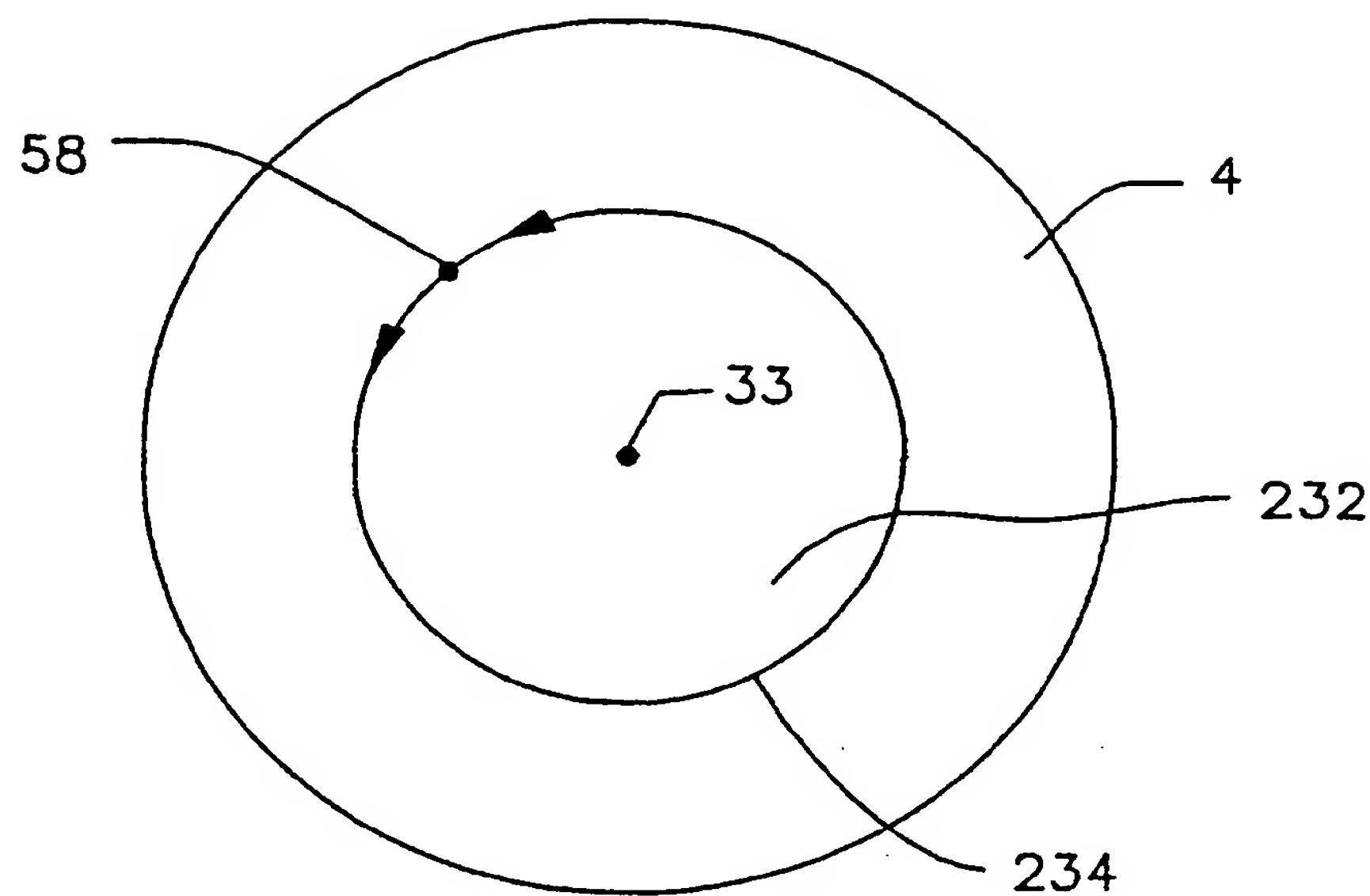
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FIG. 20
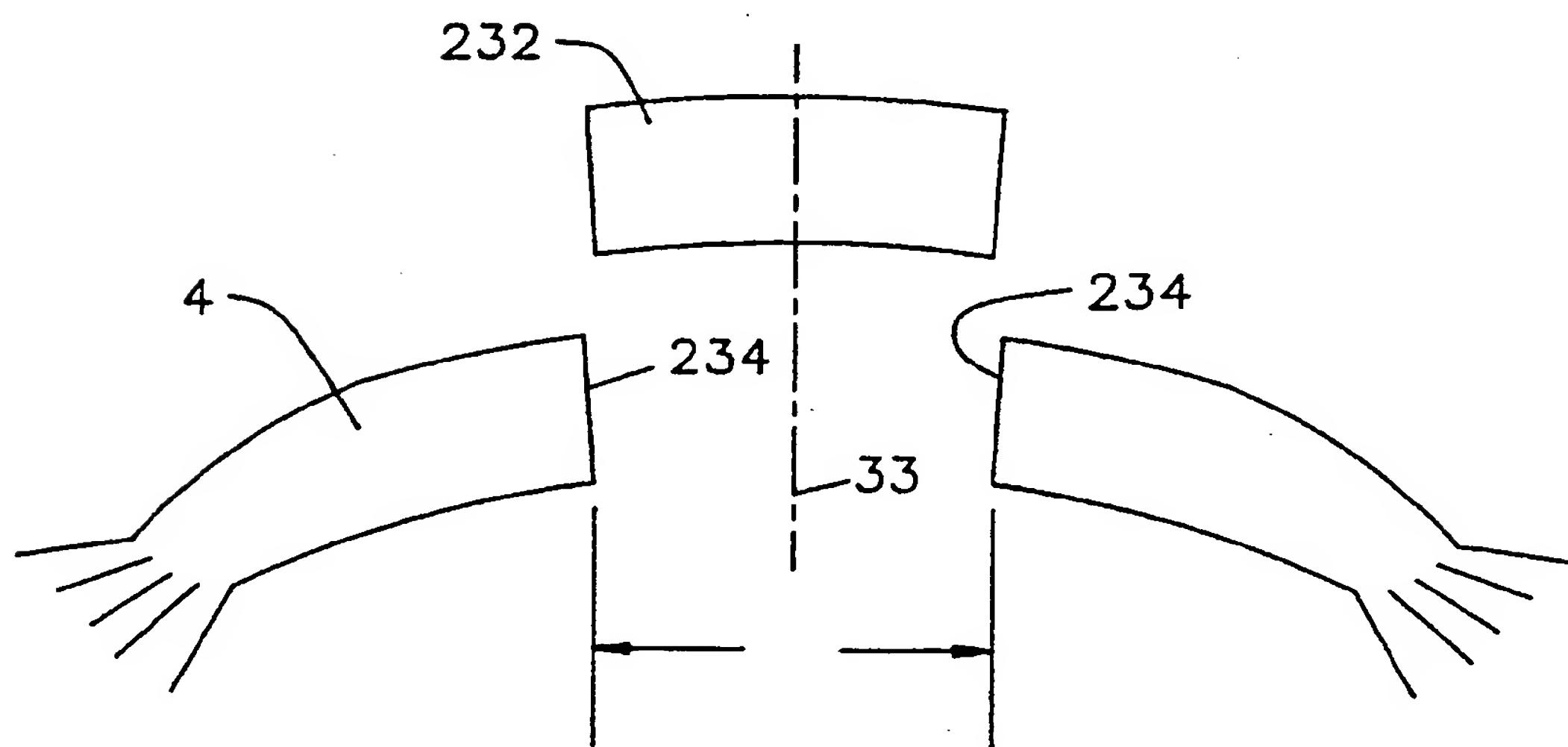
FIG. 21
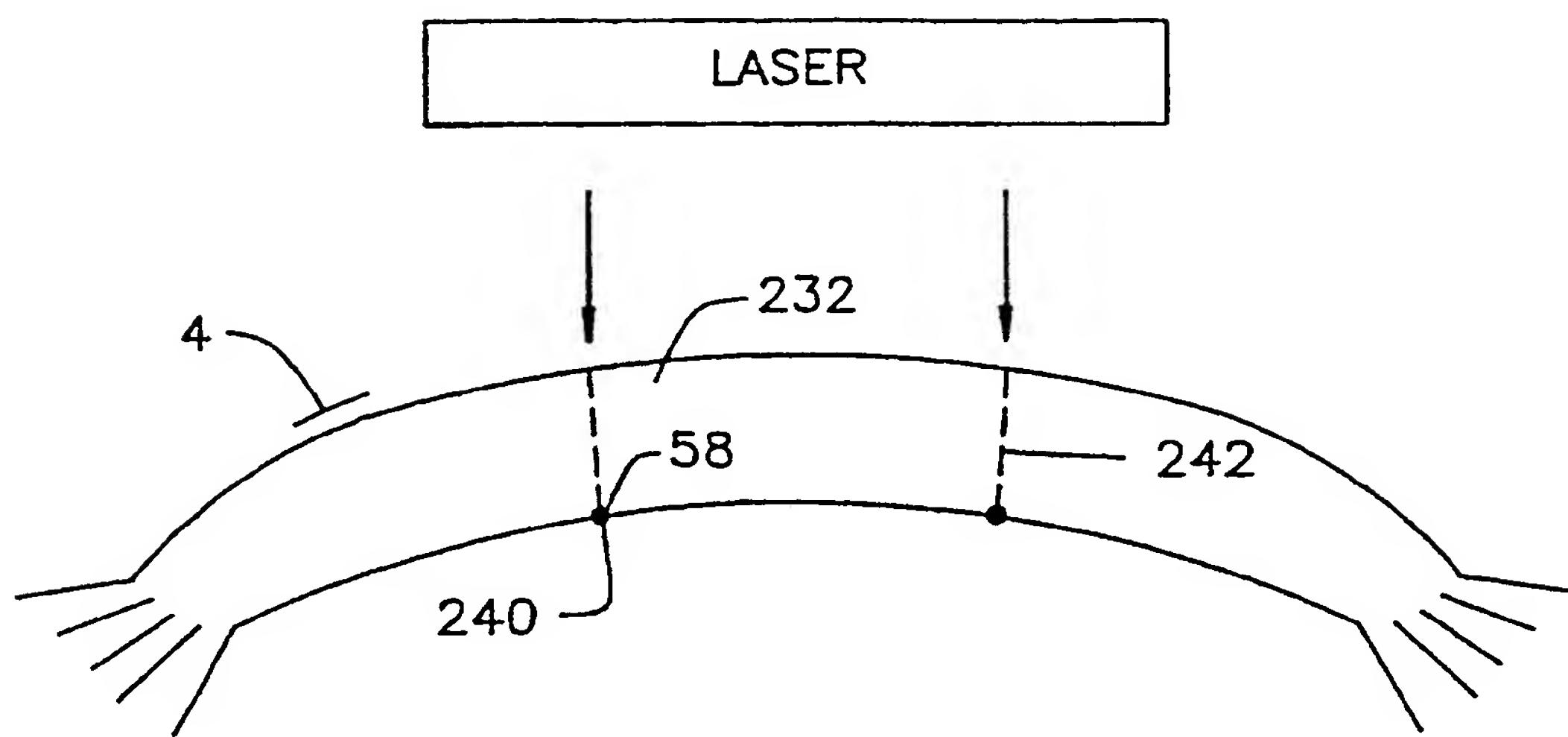
LASER

232

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242

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FIG. 22

248

252

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FIG. 23

FIG. 24

LASER

270 — 272

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14

FIG. 25

FIG. 26

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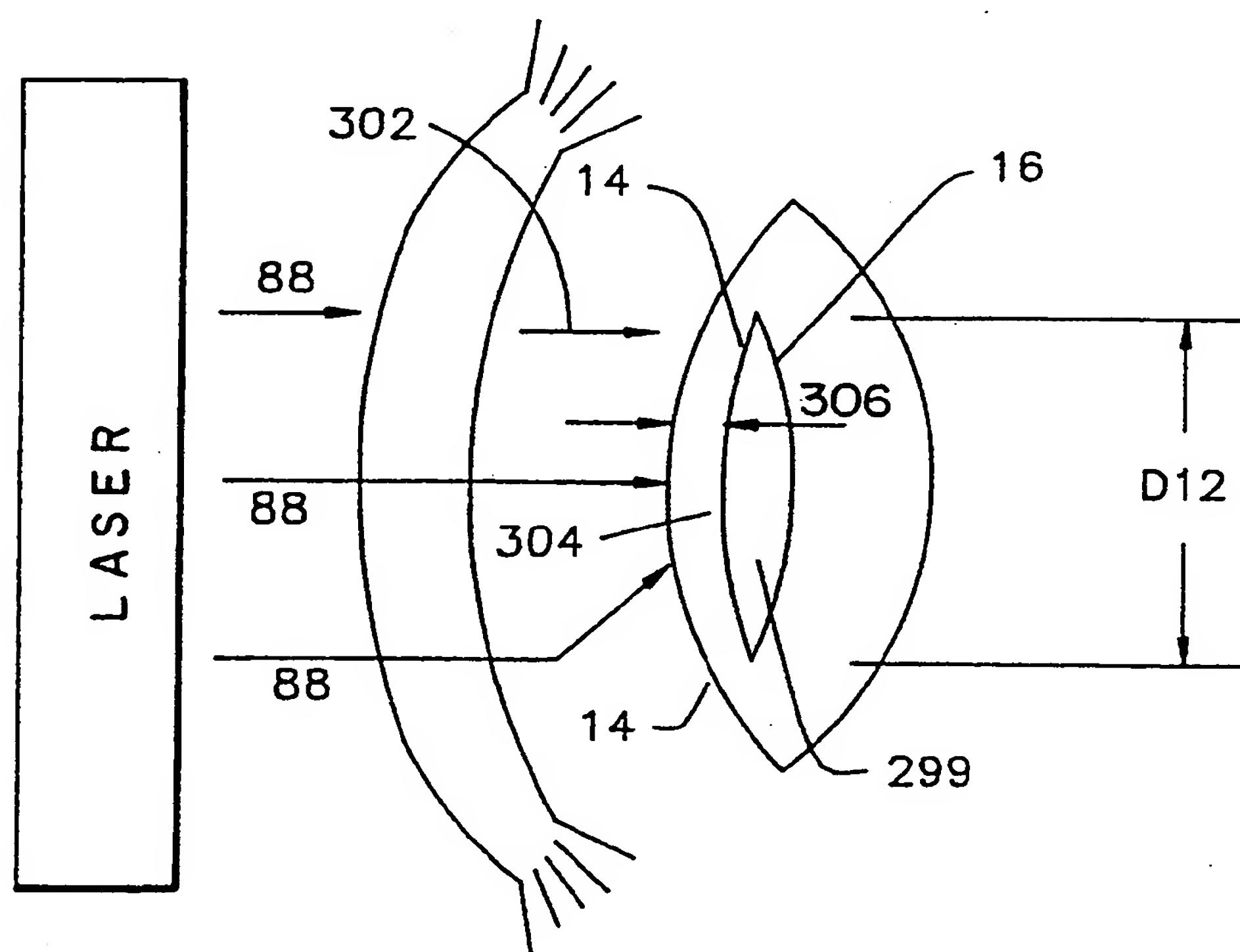
FIG. 27

FIG. 28

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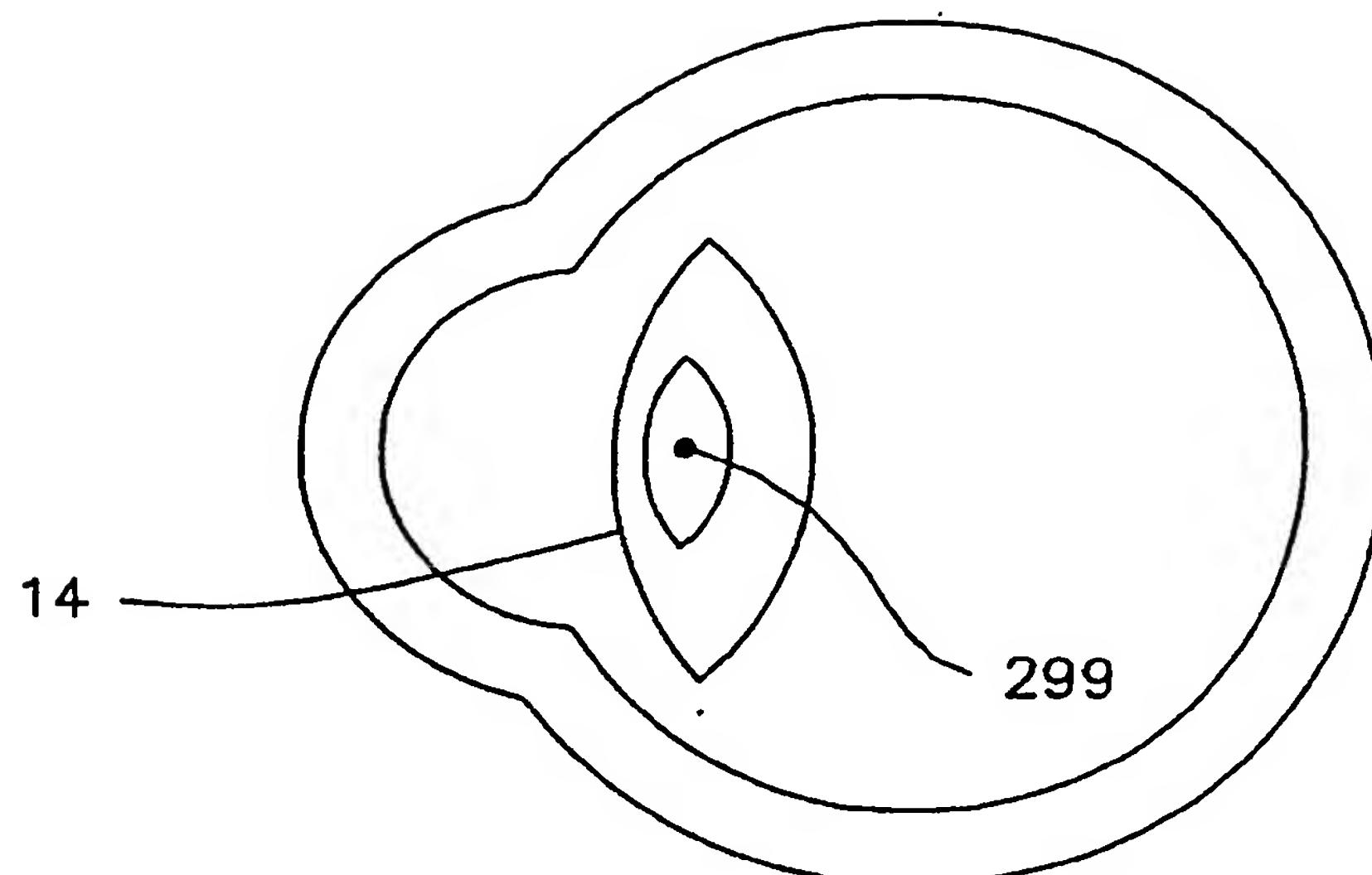
FIG. 29

FIG. 30

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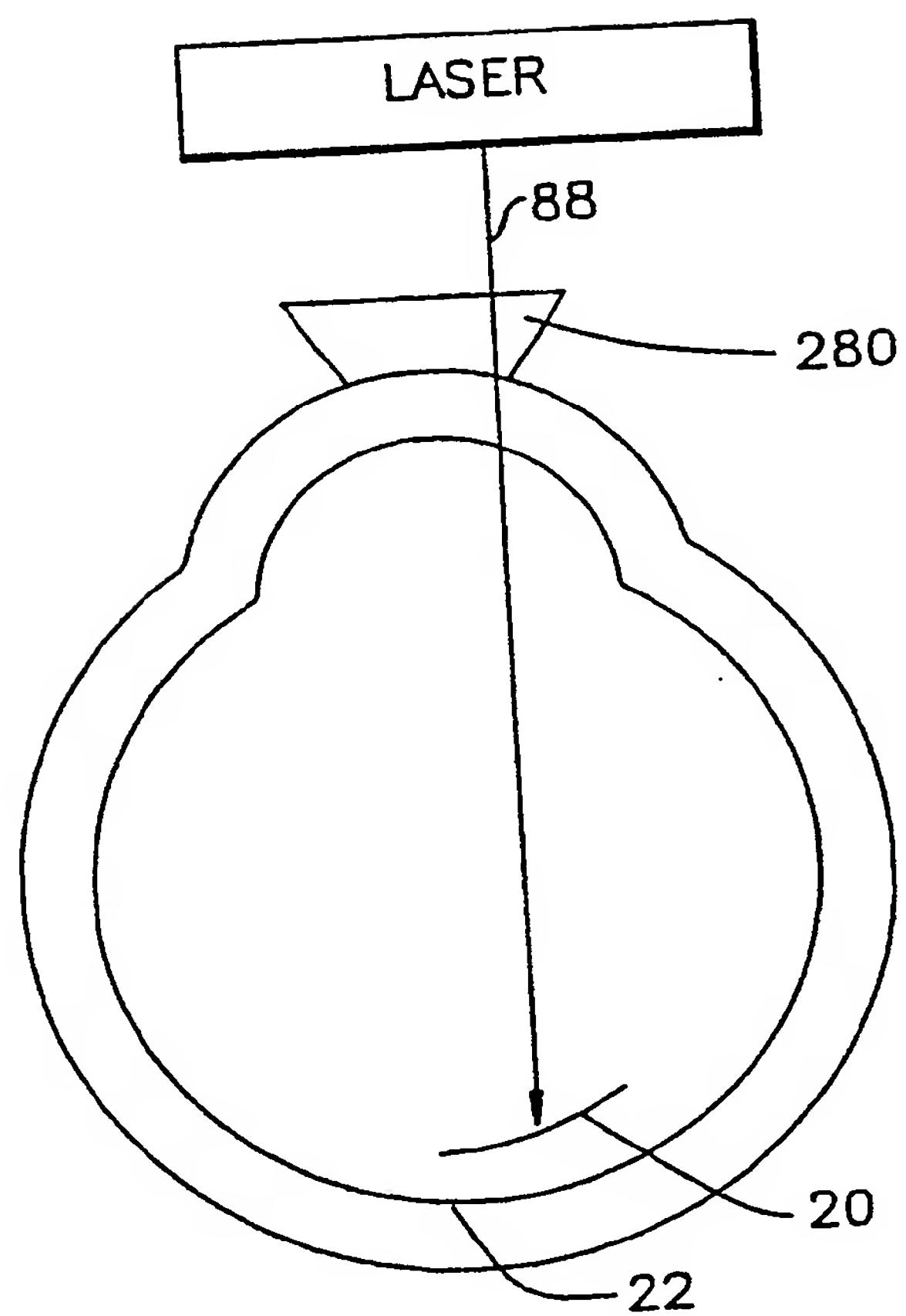
FIG. 31

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INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61N 5/02, 06
US CL :606/4

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/3-6; 128/898

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y,P	US, A, 5,163,934 (Munnerlyn) 17 November 1992. See entire document.	1-6, 8. 10 and 13
Y	US, A, 4,907,586 (Bille et al.) 13 March 1990. See column 10 lines 55-60, and column 11 lines 1-4.	11
Y	US, A, 4,464,761 (Alfano et al.) 07 August 1984. See column column 1 lines 12-14.	7, 9, 12
Y	WO, A., 87/ 07165 (Sklar et al.) 03 December 1987. See entire document.	1-6, 8, 10 and 13
A	US, A, 4,665,913 (L'Esperance, Jr.) 19 May 1987. See entire document.	1-13

[X] Further documents are listed in the continuation of Box C.   [ ] See patent family annex.

*	Special categories of cited documents:	
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier document published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	
"P"	document published prior to the international filing date but later than the priority date claimed	"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 DECEMBER 1993	20 MAR 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer SONYA C. HARRIS
Facsimile No. NOT APPLICABLE	Telephone No. (703) 308-2216

Form PCT/ISA/210 (second sheet)(July 1992)*

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,994,058 (Raven et al.) 19 February 1991. See entire document.	1-13